FINAL REPORT

STUDY TITLE

PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

STUDY NUMBER

[ ]

STUDY DIRECTOR

[ ]

STUDY INITIATION DATE

27 November 2006

STUDY COMPLETION DATE

26 September 2007

PERFORMING LABORATORY

[ ]

SPONSOR

[ ]

534006

COMPLIANCE STATEMENT

This study, designated was conducted in compliance with the United States Environmental Protection Agency (EPA) Good Laboratory Practice (GLP) Standards (40 CFR Part 792), 18 September 1989; the Organisation for Economic Cooperation and Development (OECD) Principles of Good Laboratory Practice [C (97) 186/Final], 26 November 1997; the standard operating procedures of LLC, and the protocol as approved by the sponsor. The study was GLP compliant with the following exception. A critical phase inspection was not performed by the Quality Assurance unit while the study was in progress. A Certificate of Analysis was provided by the sponsor (presented in Appendix A); the characterization analyses were conducted according to unknown standards.

26 September 2007
Date

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1. SUMMARY

1.1. OBJECTIVE

The objectives of the study were to evaluate the pharmacokinetic (in blood) and excretion profiles of the test article in rats.

1.2. STUDY DESIGN

[ ] in the vehicle, sterile water for injection, was administered intravenously once to 1 pharmacokintic (blood collection) group ([ ]; Group 1) and 1 excretion group ([ ]; Group 1) of Crl:CD(SD) rats. The dosage level was 10 mg/kg for both groups at a dosage volume of 5 mL/kg. The pharmacokinetic group consisted of 9 animals/sex and the excretion group consisted of 3 animals/sex.

All animals were observed twice daily for mortality and moribundity. Detailed physical examinations were performed at least once during the pre-treatment period. Individual body weights were recorded during acclimation, at pretest initiation, at randomization and on study day 0. Food consumption was recorded during the pretest period only.

For pharmacokinetic assessment, blood samples were collected on wet ice from 3 animals/sex prior to dosing and at approximately 2, 10, 20 and 30 minutes and 1, 3, 5, 7, 24 and 48 hours after dose administration.

For excretion profile, urine samples were collected from 3 animals/sex over the following intervals: 0-6, 6-12 and 12-24 hours post-dosing.

All pharmacokinetic and excretion group animals were euthanized and discarded without further evaluation following the final blood or urine collection.

Serum and urine concentrations of [ ] were measured using a validated LCMS/MS method. The concentrations in serum and amounts excreted in urine were used for pharmacokinetic analysis.

1.3. RESULTS AND CONCLUSIONS

After a single intravenous dose of [ ] at 10 mg/kg, systemic exposure ($AUC_{0-\infty}$) to[ ] for male rats was almost 7-fold higher than for female rats. [ ] appeared to remain mostly in the circulation in male rats (apparent volume of distribution about 0.2 L/kg), but to have extensive tissue distribution in female rats (apparent volume of distribution of more than 2.5 L/kg). The terminal elimination phase for [ ] in serum had a half-life of 9.4 and 5.4 hours for female and male rats, respectively. The half-life for [ ] in urine was 1.8 and 3.2 hours, for female and male rats respectively. Nevertheless, the percent of [ ] dose eliminated over 24 hours post-dosing in the urine of male rats and female rats was similar (approximately 65%). This can be explained by the lower amounts of [ ] available for urinary clearance in the circulation of female rats compared to male rats as suggested by the differences in the apparent volume of distribution.

In conclusion, systemic exposure ($AUC_{0-\infty}$) to [ ] for male rats was almost 7-fold higher than for female rats following a single intravenous dose of [ ] at 10 mg/kg. [ ] in the serum cleared more rapidly in the male rats than in the female rats, and the female rats had a greater volume distribution than the male rats. [ ] cleared in the urine more rapidly in the female rats than in the male rats, but most of the [ ] dose was eliminated over 12 hours post-dosing in both genders. The elimination of [ ] in the urine appeared to be mono-exponential for male rats and appeared not to be log-linear for female rats.

2. INTRODUCTION

2.1. GENERAL STUDY INFORMATION

This report presents the data from "Pharmacokinetic (In Blood) And Excretion Study Of [ ] In Rats." Due to software spacing constraints, the study title appears as "A Pharmacokinetic And Excretion Study In Rats" on the report tables.

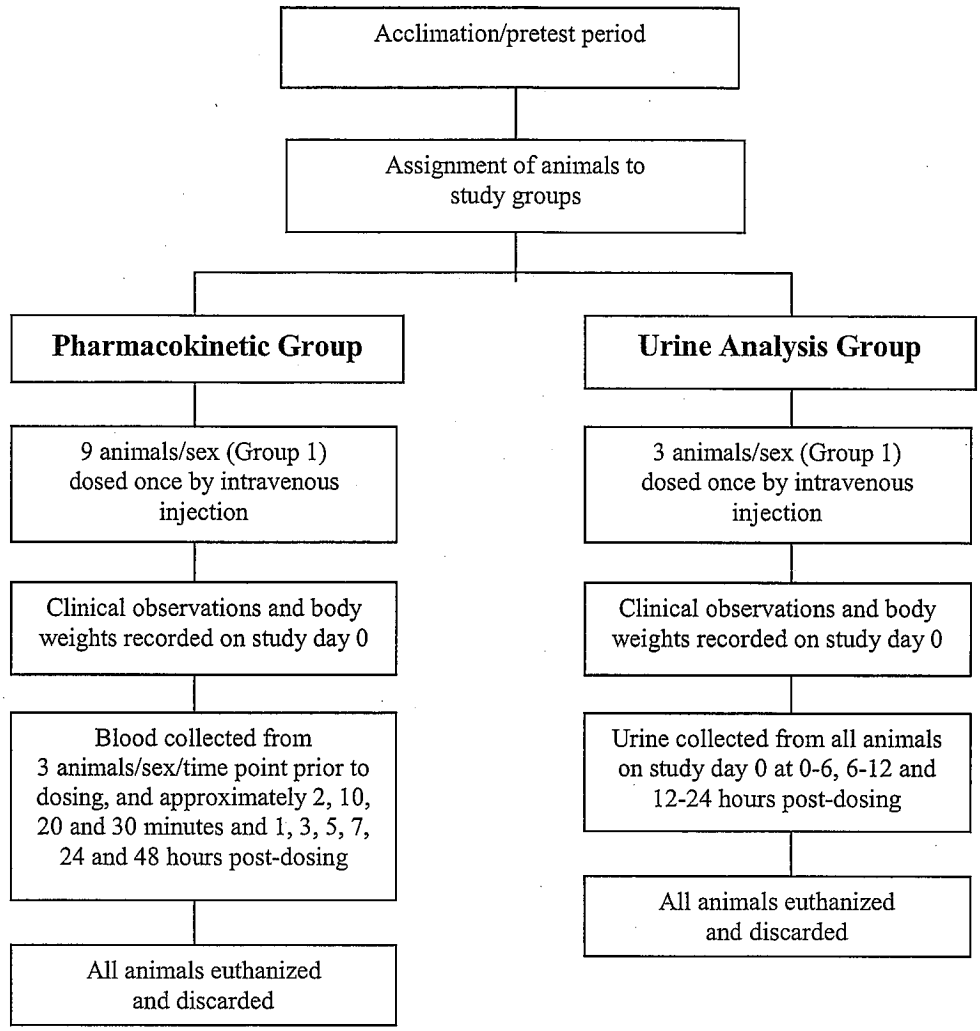
The following computer protocols were used for data collection during the study:

Computer Protocol	Type of Data Collected
[ ]	Main study data (blood collection)
[ ]	Main study data (urine collection)

2.2. KEY STUDY DATES

Date(s)	Event(s)
28 November 2006	Experimental starting date (animal receipt)
8 December 2006	Assignment to study groups
11 December 2006	Experimental start date (initiation of dose administration; study day 0)
25 July 2007	Experimental termination (completion) date (last bioanalytical analysis)

3. STUDY DESIGN



4. EXPERIMENTAL PROCEDURES - MATERIALS AND METHODS

4.1. TEST ARTICLE AND VEHICLE

4.1.1. TEST ARTICLE IDENTIFICATION

The test article, [ ]
was received from Miki & Co., LTD, Chuo-Ku, Japan, on 29 November 2006, as follows:

Identification	Quantity Received	Physical Description
[ ] [log no. 7216A]	1 bottle Gross weight: 347.3 g	Clear, colorless liquid

A Certificate of Analysis for the test article was provided by the sponsor and is presented in Appendix A. The purity of the test article was 99.0%. The test article was stored at room temperature and was considered stable under this condition. A reserve sample of the test article (0.333 g) was collected on 1 December 2006 and stored in the Archives of [ ].

4.1.2. VEHICLE IDENTIFICATION

The vehicle used in preparation of the test article formulations was sterile water for injection, USP (lot no. C688010, exp. date: 1 August 2007, manufactured by Baxter Healthcare Corporation, Deerfield, Illinois).

4.1.3. PREPARATION

Dosing formulations were prepared at the concentrations indicated in the following table:

Group Number	Test Article	Dosage Level (mg/kg)	Dosing Concentration (mg/mL) [a]
1	[ ]	10	2

[a] = The dosing formulations were not adjusted for purity.

The test article formulation was prepared as a weight/volume (test article/vehicle) mixture. The appropriate amount of the test article was weighed into a tared, labeled storage container. A predetermined volume of the vehicle was added to the container to bring the formulation nearly to the calibration mark. The formulation was mixed with a magnetic stirrer until uniform. Additional vehicle was then added to bring the formulation to the calibration mark. The formulation was stirred until uniform and stirring continued overnight in a refrigerator. The solution was removed from the refrigerator the following morning. While in a Laminar flow hood, the formulation was sterile-filtered through a 0.22-µm syringe filter into a sterile container and capped with a septum. On the day of dose administration, the formulation was removed from the refrigerator and maintained at room temperature for approximately 1 hour prior to dosing.

The test article formulations for the pharmacokinetic group (Group 1) and excretion (Group 1) group were prepared once and stored refrigerated. The test article formulation was stirred continuously throughout the preparation, sampling and dose administration procedures. A small aliquot was removed from the formulation and the pH was measured as 2.45.

4.1.4. SAMPLING AND ANALYSES

Samples (1 mL each) for concentration and stability analyses were collected from the dosing formulation at the following times: prior to filtration, after filtration and after dose administration. Homogeneity assessments were not performed as the formulations were solutions. All analyses were conducted by the Analytical Chemistry Department, [ ]. The methodology and results of these analyses are presented in Appendix B, and the results are summarized in Section 6.1.

4.2. TEST SYSTEM

Crl:CD(SD) rats from Charles River Laboratories, Inc., Raleigh, North Carolina were used as the test system on this study. This species and strain of animal is recognized as appropriate for acute and subchronic toxicity studies. The Sprague-Dawley rat was used

because it is a widely used strain for which significant historical control data are available.

4.3. ORGANIZATION OF TEST GROUPS, DOSAGE LEVELS AND TREATMENT REGIMEN

The vehicle and test article formulations were administered as a single dose by a slow bolus intravenous injection using a sterile needle and syringe via a lateral tail vein. The dosage volume for all groups was 5 mL/kg. Individual doses were based on the study day 0 body weights to provide the correct mg/kg dosage.

The following tables present the study group assignment:

Pharmacokinetic Group [ ]

Group Number	Test Article[a]	Dosage Level (mg/kg)	Dosage Volume (mL/kg)	Number of Animals	
				Males	Females
1	[ ]	10	5	9	9

Excretion Group [ ]

Group Number	Test Article[a]	Dosage Level (mg/kg)	Dosage Volume (mL/kg)	Number of Animals	
				Males	Females
1	[ ]	10	5	3	3

[a] = The dosing formulations were not adjusted for purity.

The selected route of administration for this study was intravenous because this is an acceptable route of administration to assess pharmacokinetics and elimination profiles. The number of animals selected for this study was the minimum required to yield scientifically meaningful data and was consistent with regulatory agency expectations.

4.4. ANIMAL RECEIPT AND ACCLIMATION/PRETEST PERIOD

Fifteen male and 15 female Crl:CD(SD) rats were received in good health on 28 November 2006, from Charles River Laboratories, Inc., Raleigh, North Carolina. The animals were approximately 38 days old at receipt. Each animal was examined by a

qualified technician on the day of receipt and weighed 3 and 10 days later. Each animal was uniquely identified by a Monel® metal ear tag displaying the permanent identification number. All animals were housed for at least a 7-day acclimation/pretest period. During this period, each animal was observed twice daily for mortality and changes in general appearance or behavior.

Pretest data collection began on 1 December 2006. Individual body weights were recorded and detailed physical examinations were performed periodically during the pretest period. Food consumption data were also recorded for pretest animals prior to the initiation of dose administration. Pretest clinical observations are presented in Appendix C.

4.5. ANIMAL HOUSING

Upon arrival, all animals were housed individually in clean, stainless steel, wire-mesh cages suspended above cage-board. Animals were maintained in accordance with the *Guide for the Care and Use of Laboratory Animals* (National Research Council, 1996). The animal facilities at [ ] are accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International).

4.6. DIET, DRINKING WATER AND MAINTENANCE

The basal diet used in this study, PMI Nutrition International, LLC, Certified Rodent LabDiet® 5002, is a certified feed with appropriate analyses performed by the manufacturer and provided to [ ] . Reverse osmosis-treated (on-site) drinking water, delivered by an automatic watering system, and the basal diet were provided ad libitum throughout the study. Municipal water supplying the facility was sampled for contaminants according to the standard operating procedures. The results of the diet and water analyses are maintained at [ ] . No contaminants were present in animal feed or water at concentrations sufficient to interfere with the objectives of this study.

4.7. ENVIRONMENTAL CONDITIONS

All animals were housed throughout the acclimation period and during the dosing and sample collection phases of the study in an environmentally controlled room. The room temperature and humidity controls were set to maintain daily averages of 71 ± 5°F (22 ± 3°C) and 50 ± 20% relative humidity. Room temperature and relative humidity were controlled and monitored using the Metasys® DDC Electronic Environmental control system. These data were recorded approximately hourly and are summarized in Appendix D. Actual mean daily temperature ranged from 70.2°F to 70.6°F (21.2°C to 21.4°C) and mean daily relative humidity ranged from 29.3% to 45.9% during the study. Lights in the animal room were controlled by the Metasys® DDC Electronic Environmental control system and were set to provide a 12-hour light (0600 hours to 1800 hours)/12-hour dark photoperiod. The 12-hour light/12-hour dark photoperiod was interrupted as necessary to allow for the performance of protocol-specified activities. Air handling units were set to provide a minimum of 10 fresh air changes per hour.

4.8. ASSIGNMENT OF ANIMALS TO TREATMENT GROUPS

On 8 December 2006 (3 days prior to the initiation of dose administration), all available rats were weighed and examined in detail for physical abnormalities. These data were collected using the [ ] and reviewed by the study director. The animals judged suitable for assignment to the study were selected for use in a computerized randomization procedure. A printout containing the animal numbers, corresponding body weights and individual group assignments was generated based on body weight stratification in a block design. The animals were then arranged into groups according to the printout. Individual body weights at randomization were within ± 20% of the mean for each sex. The pharmacokinetic group consisted of 9 males and 9 females. The excretion group consisted of 3 males and 3 females. The selected animals were approximately 7 weeks old at the initiation of dose administration; individual body weights ranged from 219 g to 248 g for males and from 157 g to 186 g

for females in the pharmacokinetic group, and from 225 g to 239 g for males and from 164 g to 174 g for females in the excretion group.

5. PARAMETERS EVALUATED

5.1. CLINICAL OBSERVATIONS AND SURVIVAL (BOTH PHASES)

All animals were observed twice daily, once in the morning and once in the afternoon, for mortality and moribundity. Detailed physical examinations were conducted approximately weekly during the pretest period.

5.2. BODY WEIGHTS (BOTH PHASES)

Individual body weights were recorded during pretest, at randomization and on study day 0.

5.3. FOOD CONSUMPTION (BOTH PHASES)

Individual food consumption was recorded during the pretest period.

5.4. TOXICOKINETICS

The methods and results of the pharmacokinetic and excretion analyses are presented in Appendix E, and the interpretation of the toxicokinetic data are presented in Appendix F.

5.5. PHARMACOKINETIC PROFILE (PHARMACOKINETIC PHASE)

Blood samples (approximately 0.5 mL each) for test article serum level determinations were collected at prior to dosing and at approximately 2, 10, 20 and 30 minutes and 1, 3, 5, 7, 24 and 48 hours after dose administration. Blood was collected via the retro-orbital sinus from isoflurane-anesthetized animals into tubes containing no anticoagulant. Samples were allowed to clot at room temperature, after which the samples were stored chilled until serum preparation. Serum was separated using a refrigerated centrifuge and frozen at approximately -20°C until transferred to the [ ] for analysis.

5.5.1. EXCRETION PROFILE (EXCRETION PHASE)

Urine was collected on wet ice over the following intervals: 0-6, 6-12 and 12-24 hours post-dosing. Animals were transferred to plastic metabolism cages for urine collection. At each collection interval, the cages were rinsed using a documented amount of

deionized water. Urine samples and cage rinses were frozen with minimal delay at approximately -20°C and stored at approximately -20°C until transferred to the [ ] for analysis.

5.6. STUDY TERMINATION (BOTH PHASES)

All animals were euthanized by carbon dioxide inhalation following the final blood or urine collection and discarded without further evaluation.

5.7. STATISTICAL METHODS

Statistical analyses were not conducted on this study.

5.8. DATA RETENTION

The sponsor has title to all documentation records, raw data, specimens or other work product generated during the performance of the study. All work product generated by [ ] , including raw paper data and specimens, are retained in the Archives at [ ] as specified in the study protocol.

The reserve sample of the test article, pertinent electronic storage media and the original final report are retained in the Archives at [ ] incompliance with regulatory requirements.

6. RESULTS AND DISCUSSION (BOTH PHASES)

6.1. ANALYTICAL CHEMISTRY

Analytical Chemistry Report: Appendix B

The analyzed formulation was found to contain the amount of test article prescribed in the protocol (105% of target post-filter). Results of the concentration analyses of the dosing formulation are summarized below.

Text Table 3. Results of Concentration Analyses

	Mean Concentration, mg/mL (% of Target), Post-Filter
	Group 1
Date of Preparation	(2 mg/mL)
6, 7 December 2006	105%

The test article was found to be stable in the formulations when stored refrigerated for 5 days (102% of the corresponding time-zero value).

6.2. CLINICAL OBSERVATIONS AND SURVIVAL

Summary Data: Appendix C

Individual Data: Tables 1, 2, 3, 4

All animals survived to the scheduled euthanasia. There were no test article-related clinical observations.

6.3. BODY WEIGHTS

Individual Data: Tables 5, 6

Body weights were collected for dose calculation purposes only.

6.4. TOXICOKINETICS

Bioanalytical Report: Appendix E

Toxicokinetic Report: Appendix F

The concentration of [ ] in the serum, urine, and cage rinse samples was measured using a validated LC-MS/MS method. The serum concentration immediately following the intravenous dose was estimated based on a regression analysis of the measured values. The mean concentrations in serum and mean amounts excreted in urine plus cage rinse were used for pharmacokinetic analysis.

The pharmacokinetic parameters for [ ] are summarized in the following table:

PHARMACOKINETIC RESULTS FOR [ ]

[ ] 10 mg/kg Intravenous Dose	SERUM						URINE†		
	C_0* (ng/mL)	$AUC_{0-\infty}$ (ng×h/mL)	K_{el} (h^{-1})	Half-life** (h)	Cl (L/h×kg)	V_d (L/kg)	K_{el} (h^{-1})	Half-life*** (h)	% of Dose Elimi-nated
Males	69775	373393	0.127	5.4	0.0268	0.210	0.215	3.2	67.3
Females	102835	53137	0.074	9.4	0.188	2.55	0.392	1.8	64.0

*Values were estimated.
**For the terminal elimination phase.
***For urinary elimination.
†Urine plus cage rinse

After a single intravenous dose of [ ] at 10 mg/kg, systemic exposure ($AUC_{0-\infty}$) to[ ] for male rats was almost 7-fold higher than for female rats. [ ] appeared to remain mostly in the circulation in male rats (apparent volume of distribution about 0.2 L/kg), but to have extensive tissue distribution in female rats (apparent volume of distribution of more than 2.5 L/kg). The terminal elimination phase for [ ] in serum had a half-life of 9.4 and 5.4 hours for female and male rats, respectively. The half-life for [ ] in urine was 1.8 and 3.2 hours, for female and male rats respectively. Nevertheless, the percent of [ ] dose eliminated over 24 hours post-dosing in the urine of male rats and female rats was similar (approximately 65%). This can be explained by the lower amounts of [ ] available for urinary clearance in the circulation of female rats

compared to male rats as suggested by the differences in the apparent volume of distribution.

7. CONCLUSIONS

In conclusion, systemic exposure ($AUC_{0-\infty}$) to [ ] for male rats was almost 7-fold higher than for female rats following a single intravenous dose of [ ] at 10 mg/kg. [ ] in the serum cleared more rapidly in the male rats than in the female rats, and the female rats had a greater volume distribution than the male rats. [ ] cleared in the urine more rapidly in the female rats than in the male rats, but most of the [ ] dose was eliminated over 12 hours post-dosing in both genders. The elimination of [ ] in the urine appeared to be mono-exponential for male rats and appeared not to be log-linear for female rats.

9. QUALITY ASSURANCE UNIT STATEMENT

9.1. PHASES INSPECTED

Date(s) of Inspection(s)	Phase Inspected	Date(s) Findings Reported to Study Director	Date(s) Findings Reported to Management	Auditor(s)
16-Feb-2007	Draft Report (Analytical Appendix)	16-Feb-2007	21-Mar-2007	M.Stauffer
12-Feb-2007 13-Feb-2007 15-Feb-2007 16-Feb-2007	Study Records (A-1, A-2)	16-Feb-2007	21-Mar-2007	M.Stauffer
22-Feb-2007	Study Records (Rx-1)	22-Feb-2007	21-Mar-2007	K.Shaner
22-Feb-2007	Study Records (I-1)	22-Feb-2007	21-Mar-2007	K.Shaner
22-Feb-2007	Study Records (C-1)	22-Feb-2007	21-Mar-2007	K.Shaner
19-Apr-2007 20-Apr-2007 21-Apr-2007 23-Apr-2007	Study Records (B-1, B-2, B-3)	23-Apr-2007	24-May-2007	E.Crookshank
15-May-2007	Draft Report (Bioanalytical Appendix)	15-May-2007	20-Jun-2007	E.Crookshank
06-Jun-2007 07-Jun-2007	Draft Report (Toxicokinetic Appendix)	07-Jun-2007	19-Jul-2007	E.Crookshank
06-Jun-2007 07-Jun-2007	Study Records (C-1 Supplemental, Toxicokinetic Data)	07-Jun-2007	19-Jul-2007	E.Crookshank
12-Jun-2007 13-Jun-2007	Draft Report excluding Bioanalytical Report, Toxicokinetic Report, and Analyses of Dosing Formulations Appendix	13-Jun-2007	19-Jul-2007	K.Shaner
17-Sep-2007	Study Records (B-1, B-3; Long-term and freeze thaw stability)	17-Sep-2007	25-Sep-2007	E.Crookshank
18-Sep-2007	Revised Draft Report (Bioanalytical Appendix)	18-Sep-2007	25-Sep-2007	E.Crookshank

This study was inspected in accordance with the U.S. EPA Good Laboratory Practice (GLP) Standards (40 CFR Part 792), the OECD Principles of Good Laboratory Practice, the Japanese MAFF Good Laboratory Practice Standards, the standard operating

procedures of [ ] and the sponsor's protocol and protocol amendments, with the following exceptions. The data located in Appendix A (Certificate of Analysis) were the responsibility of the sponsor. A critical phase inspection was not performed by the Quality Assurance unit while the study was in progress. Quality Assurance findings, derived from the inspections during the conduct of the study and from the inspections of the raw data and draft report, are documented and have been reported to the study director.

This report accurately reflects the data generated during the study. The methods and procedures used in the study were those specified in the protocol, its amendments and the standard operating procedures of [ ].

The raw data, the retention sample and the final report will be stored in the Archives at [ ] or another location specified by the sponsor.

10. REFERENCES

National Research Council. *Guide for the Care and Use of Laboratory Animals,* Institute of Laboratory Animal Resources, Commission on Life Sciences; National Academy Press: Washington, DC, **1996**.

11. DEVIATIONS FROM THE PROTOCOL

This study was conducted in accordance with the protocol and protocol amendments, except for the following.

- **Protocol Section 6.1** states that animals will be housed 3 per cage by sex for 2 to 4 days following receipt. After consultation with the study director the animals were housed individually.
- **Protocol Section 6.2** states that average daily humidity would be 50 ± 20%. There were 5 or more excursions for humidity and the daily average humidity was outside acceptable range on 2 December 2006 (study day -9); the average relative humidity value for this day was 29.3%.
- **Protocol Section 7.5.2** states that analyses to demonstrate the stability of the test article formulation for the expected period of refrigerated storage between formulation and dosing will be conducted before the initiation of dosing. The dosing aliquot was inadvertently not collected until after dosing.

These deviations did not negatively impact the quality or integrity of the data nor the outcome of the study.

TABLES 1 - 6

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TABLE 1 (PHARMACOKINETIC PHASE)
A PHARMACOKINETIC AND EXCRETION STUDY IN RATS
INDIVIDUAL SURVIVAL AND DISPOSITION

ANIMAL	SEX	GROUP	TYPE OF DEATH	AGE IN WEEKS A	DATE OF DEATH	DAYS ON STUDY
46662	M	10 MG/KG	SCHEDULED EUTHANASIA	7	13-DEC-06	2
46663	M	10 MG/KG	SCHEDULED EUTHANASIA	7	13-DEC-06	2
46665	M	10 MG/KG	SCHEDULED EUTHANASIA	7	13-DEC-06	2
46666	M	10 MG/KG	SCHEDULED EUTHANASIA	7	13-DEC-06	2
46669	M	10 MG/KG	SCHEDULED EUTHANASIA	7	13-DEC-06	2
46672	M	10 MG/KG	SCHEDULED EUTHANASIA	7	13-DEC-06	2
46673	M	10 MG/KG	SCHEDULED EUTHANASIA	7	13-DEC-06	2
46674	M	10 MG/KG	SCHEDULED EUTHANASIA	7	13-DEC-06	2
46676	M	10 MG/KG	SCHEDULED EUTHANASIA	7	13-DEC-06	2

A = CALCULATED TO THE NEAREST WHOLE WEEK USING THE MEAN AGE IN WEEKS AT INITIATION OF DOSING (7)

ANIMAL	SEX	GROUP	TYPE OF DEATH	AGE IN WEEKS A	DATE OF DEATH	DAYS ON STUDY
46678	F	10 MG/KG	SCHEDULED EUTHANASIA	7	13-DEC-06	2
46679	F	10 MG/KG	SCHEDULED EUTHANASIA	7	13-DEC-06	2
46680	F	10 MG/KG	SCHEDULED EUTHANASIA	7	13-DEC-06	2
46681	F	10 MG/KG	SCHEDULED EUTHANASIA	7	13-DEC-06	2
46684	F	10 MG/KG	SCHEDULED EUTHANASIA	7	13-DEC-06	2
46685	F	10 MG/KG	SCHEDULED EUTHANASIA	7	13-DEC-06	2
46686	F	10 MG/KG	SCHEDULED EUTHANASIA	7	13-DEC-06	2
46688	F	10 MG/KG	SCHEDULED EUTHANASIA	7	13-DEC-06	2
46691	F	10 MG/KG	SCHEDULED EUTHANASIA	7	13-DEC-06	2

A = CALCULATED TO THE NEAREST WHOLE WEEK USING THE MEAN AGE IN WEEKS AT INITIATION OF DOSING (7)

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TABLE 2 (EXCRETION PHASE)
A PHARMACOKINETIC AND EXCRETION STUDY IN RATS
INDIVIDUAL SURVIVAL AND DISPOSITION

ANIMAL	SEX	GROUP	TYPE OF DEATH	AGE IN WEEKS A	DATE OF DEATH	DAYS ON STUDY
46664	M	10 MG/KG	SCHEDULED EUTHANASIA	7	12-DEC-06	1
46667	M	10 MG/KG	SCHEDULED EUTHANASIA	7	12-DEC-06	1
46670	M	10 MG/KG	SCHEDULED EUTHANASIA	7	12-DEC-06	1
46682	F	10 MG/KG	SCHEDULED EUTHANASIA	7	12-DEC-06	1
46683	F	10 MG/KG	SCHEDULED EUTHANASIA	7	12-DEC-06	1
46690	F	10 MG/KG	SCHEDULED EUTHANASIA	7	12-DEC-06	1

A = CALCULATED TO THE NEAREST WHOLE WEEK USING THE MEAN AGE IN WEEKS AT INITIATION OF DOSING (7)

TABLE 3 (DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS - PHARMACOKINETIC PHASE)

PROJECT NO.:534006A — A PHARMACOKINETIC AND EXCRETION STUDY IN RATS —

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 12-11-06 TO 12-13-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
46662	M	10 MG/KG	NORMAL	12-11-06	8:09	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
46662	M	10 MG/KG	DISPOSITION	12-13-06	11:41	P	EUTHANIZED BY CO2 AND DISCARDED
46663	M	10 MG/KG	NORMAL	12-11-06	8:09	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
46663	M	10 MG/KG	DISPOSITION	12-13-06	11:41	P	EUTHANIZED BY CO2 AND DISCARDED
46665	M	10 MG/KG	NORMAL	12-11-06	8:10	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
46665	M	10 MG/KG	DISPOSITION	12-13-06	11:42	P	EUTHANIZED BY CO2 AND DISCARDED
46666	M	10 MG/KG	NORMAL	12-11-06	8:10	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
46666	M	10 MG/KG	DISPOSITION	12-13-06	11:42	P	EUTHANIZED BY CO2 AND DISCARDED
46669	M	10 MG/KG	NORMAL	12-11-06	8:10	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
46669	M	10 MG/KG	DISPOSITION	12-13-06	11:42	P	EUTHANIZED BY CO2 AND DISCARDED
46672	M	10 MG/KG	NORMAL	12-11-06	8:11	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
46672	M	10 MG/KG	DISPOSITION	12-13-06	11:42	P	EUTHANIZED BY CO2 AND DISCARDED
46673	M	10 MG/KG	NORMAL	12-11-06	8:11	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
46673	M	10 MG/KG	DISPOSITION	12-13-06	11:42	P	EUTHANIZED BY CO2 AND DISCARDED
46674	M	10 MG/KG	NORMAL	12-11-06	8:11	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
46674	M	10 MG/KG	DISPOSITION	12-13-06	11:42	P	EUTHANIZED BY CO2 AND DISCARDED
46676	M	10 MG/KG	NORMAL	12-11-06	8:11	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
46676	M	10 MG/KG	DISPOSITION	12-13-06	11:42	P	EUTHANIZED BY CO2 AND DISCARDED
46678	F	10 MG/KG	NORMAL	12-11-06	8:12	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
46678	F	10 MG/KG	DISPOSITION	12-13-06	11:42	P	EUTHANIZED BY CO2 AND DISCARDED
46679	F	10 MG/KG	NORMAL	12-11-06	8:12	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
46679	F	10 MG/KG	DISPOSITION	12-13-06	11:42	P	EUTHANIZED BY CO2 AND DISCARDED
46680	F	10 MG/KG	NORMAL	12-11-06	8:12	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
46680	F	10 MG/KG	DISPOSITION	12-13-06	11:42	P	EUTHANIZED BY CO2 AND DISCARDED
46681	F	10 MG/KG	NORMAL	12-11-06	8:13	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
46681	F	10 MG/KG	DISPOSITION	12-13-06	11:42	P	EUTHANIZED BY CO2 AND DISCARDED
46684	F	10 MG/KG	NORMAL	12-11-06	8:13	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
46684	F	10 MG/KG	DISPOSITION	12-13-06	11:42	P	EUTHANIZED BY CO2 AND DISCARDED
46685	F	10 MG/KG	NORMAL	12-11-06	8:13	P	NO SIGNIFICANT CLINICAL OBSERVATIONS

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

TABLE 3 (DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS - PHARMACOKINETIC PHASE)

PROJECT NO.:534006A A PHARMACOKINETIC AND EXCRETION STUDY IN RATS

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 12-11-06 TO 12-13-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
46685	F	10 MG/KG	DISPOSITION	12-13-06	11:42	P	EUTHANIZED BY CO2 AND DISCARDED
46686	F	10 MG/KG	NORMAL	12-11-06	8:13	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
46686	F	10 MG/KG	DISPOSITION	12-13-06	11:42	P	EUTHANIZED BY CO2 AND DISCARDED
46688	F	10 MG/KG	NORMAL	12-11-06	8:14	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
46688	F	10 MG/KG	DISPOSITION	12-13-06	11:42	P	EUTHANIZED BY CO2 AND DISCARDED
46691	F	10 MG/KG	NORMAL	12-11-06	8:14	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
46691	F	10 MG/KG	DISPOSITION	12-13-06	11:42	P	EUTHANIZED BY CO2 AND DISCARDED

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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TABLE 4 (DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS - EXCRETION PHASE)

PROJECT NO.:534006B A PHARMACOKINETIC AND EXCRETION STUDY IN RATS

INDIVIDUAL CLINICAL OBSERVATIONS

TABLE RANGE: 12-11-06 TO 12-12-06

ANIMAL	SEX	GROUP	CATEGORY	DATE	TIME	GRADE	OBSERVATIONS
46664	M	10 MG/KG	NORMAL	12-11-06	8:16	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
46664	M	10 MG/KG	DISPOSITION	12-12-06	12:00	P	EUTHANIZED BY CO2 AND DISCARDED
46667	M	10 MG/KG	NORMAL	12-11-06	8:17	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
46667	M	10 MG/KG	DISPOSITION	12-12-06	12:01	P	EUTHANIZED BY CO2 AND DISCARDED
46670	M	10 MG/KG	NORMAL	12-11-06	8:17	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
46670	M	10 MG/KG	DISPOSITION	12-12-06	12:01	P	EUTHANIZED BY CO2 AND DISCARDED
46682	F	10 MG/KG	NORMAL	12-11-06	8:17	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
46682	F	10 MG/KG	DISPOSITION	12-12-06	12:01	P	EUTHANIZED BY CO2 AND DISCARDED
46683	F	10 MG/KG	NORMAL	12-11-06	8:17	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
46683	F	10 MG/KG	DISPOSITION	12-12-06	12:01	P	EUTHANIZED BY CO2 AND DISCARDED
46690	F	10 MG/KG	NORMAL	12-11-06	8:18	P	NO SIGNIFICANT CLINICAL OBSERVATIONS
46690	F	10 MG/KG	DISPOSITION	12-12-06	12:01	P	EUTHANIZED BY CO2 AND DISCARDED

GRADE CODE: 1 - SLIGHT 2 - MODERATE 3 - SEVERE P - PRESENT

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PROJECT NO.:534006A

TABLE 5 (PHARMACOKINETIC PHASE)
A PHARMACOKINETIC AND EXCRETION STUDY IN RATS
INDIVIDUAL BODY WEIGHTS [G]

MALE GROUP: 10 MG/KG

DAY	-10	-3	0
ANIMAL			
46662	152.	218.	241.
46663	153.	227.	248.
46665	142.	206.	226.
46666	138.	201.	223.
46669	145.	210.	236.
46672	147.	221.	242.
46673	137.	207.	233.
46674	150.	207.	228.
46676	141.	201.	219.
MEAN	145.	211.	233.
S.D.	5.9	9.1	9.7
N	9	9	9

FEMALE GROUP: 10 MG/KG

DAY	-10	-3	0
ANIMAL			
46678	120.	155.	162.
46679	139.	174.	186.
46680	138.	163.	166.
46681	107.	162.	162.
46684	131.	170.	177.
46685	122.	151.	157.
46686	140.	175.	186.
46688	126.	157.	163.
46691	117.	162.	167.
MEAN	127.	163.	170.
S.D.	11.3	8.4	10.8
N	9	9	9

PROJECT NO.:534006B

TABLE 6 (EXCRETION PHASE)
A PHARMACOKINETIC AND EXCRETION STUDY IN RATS
INDIVIDUAL BODY WEIGHTS [G]

MALE GROUP: 10 MG/KG

DAY	-10	-3	0
ANIMAL			
46664	144.	206.	225.
46667	147.	216.	239.
46670	146.	213.	235.
MEAN	146.	212.	233.
S.D.	1.5	5.1	7.2
N	3	3	3

FEMALE GROUP: 10 MG/KG

DAY	-10	-3	0
ANIMAL			
46682	135.	167.	168.
46683	136.	164.	174.
46690	140.	161.	164.
MEAN	137.	164.	169.
S.D.	2.6	3.0	5.0
N	3	3	3

APPENDIX A

Certificate of Analysis (Sponsor Provided Data)

	Item	Unit	Analysis Results	
1		AREA%	99.62	
2				
3	unknown	AREA%	0.005	
4	unknown		0.005	
5	unknown		0.058	
6	unknown		0.010	
7	unknown		0.029	
8	unknown		0.183	
9	unknown		0.024	
10	unknown		0.035	
11	unknown		0.027	
12				
13				
14				
15				
16				
17				
18				
19				
20				

(This is stable for 3 years in room temperature.)

Note: The issue of this analysis shall be recognized as authorized values herein given by the Manager, Quality Assurance Office.

DEC 2

APPENDIX B

Analyses Of Dosing Formulations [ ]

PHARMACOKINETIC (IN BLOOD) AND EXCRETION STUDY OF [ ] IN RATS

Analyses Of Dosing Formulations

[ ]

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1. SUMMARY

This report provides a detailed description of a high performance liquid chromatography tandem mass spectrometry method in the negative Turbo ionspray mode for the determination of [ ] [ ] concentration in sterile water. Method specificity/selectivity, calibration reproducibility, precision and accuracy were assessed and validated.

Quantitation was performed using calibration standards in the range of 250 to 3000 ng [ ]/mL. The inter-set variability of the back-calculated standard concentrations ranged from 0.95% to 2.4% relative standard deviation (RSD). The inter-set mean standard concentrations had percent relative error (%RE) values ranging from -1.4% to 1.1%.

Precision and accuracy were verified by the analysis of quality control (QC) samples prepared at 2.00 mg [ ]/mL in sterile water. The inter-set variability of the calculated QC concentration (precision) was 5.2% RSD. The inter-session mean QC concentration had a %RE value (accuracy) of 4.2%.

The formulation used for dosing was prepared at an [ ] concentration of 2 mg/mL and was assessed for test article concentration prior to and after filtration. The post-filtration results met the standard operating procedure (SOP) requirements, i.e., the concentration was within the acceptable limits (within 90% to 110% of target concentration).

In addition, test article stability in the formulation prepared at 2 mg [ ]/mL was evaluated for up to 5 days of refrigerated storage. The test article in the formulation met the [ ] SOP requirement for stability, i.e., the mean post-storage analyte concentration was not less than 90% of the time-zero concentration.

2. INTRODUCTION

This report provides a detailed description of a high performance liquid chromatography tandem mass spectrometry (HPLC/MS/MS) method in the negative Turbo ionspray mode for the determination of [

]concentration in sterile water. Method specificity/selectivity, ruggedness, calibration reproducibility, precision and accuracy were assessed and validated. In addition, dosing formulations were analyzed to confirm test article concentration and stability following refrigerated storage for 5 days.

3. EXPERIMENTAL

3.1. INSTRUMENT

A Spark Holland, Inc. Symbiosis Pharma System was used for the HPLC analysis. The Symbiosis Pharma consisted of a gradient pump set, a Reliance autosampler with Conditioned Stacker and a Spark Holland Mistral column heater. An Applied Biosystems, Inc. API 5000 tandem mass spectrometer equipped with TurboIonSpray was used for the mass monitoring. Data acquisition and analysis were performed using Analyst® 1.4.1. (Note: the retention and run time may have varied depending on column performance. Mass spectrometer conditions may have varied depending on mass spectrometer performance).

3.2. HIGH PERFORMANCE LIQUID CHROMATOGRAPHY

Column:	ACE C8 50 × 2.1 mm with a C8 guard cartridge, or equivalent
Column Temperature:	28°C to 30°C
Mobile Phase:	2 mM ammonium acetate in 70:30 deionized water:acetonitrile
Flow Rate:	0.3 mL/minute
Detector:	Mass spectrometer with conditions as described in Section 3.3. (Mass Spectrometry)

Injection Volume:	5 µL
Retention Time:	Approximately 3.2 minutes for [ ]
Run Time:	5 minutes

3.3. MASS SPECTROMETRY

Acquisition Parameters

Scan Type:	Multiple reaction monitoring (MRM)
Polarity:	Negative
Scan Mode:	N/A
Ion Source:	Turbo Spray
Resolution Q1:	Unit
Resolution Q3:	Unit
Intensity Threshold:	0.00 cps
Settling Time:	0.00 msec
MR Pause:	5.0070 msec
MCA:	No
Step Size:	0.00 amu

Analyte	Q1 Mass (amu)	Q3 Mass (amu)	Dwell (msec)	Parameter	Start/Stop
[ ]	[ ]	[ ]	[ ]	DP	30/-30
				CE	-11/-11
				CXP	-4.0/-4.0

DP = Declustering potential
CE = Collision energy
CXP = Collision cell exit potential

Parameter Table

CUR (Curtain Gas):	10.00
GS1 (Gas 1):	70.00
GS2 (Gas 2):	20.00
IS (IonSpray Voltage):	-4000.00
TEM (Temperature):	450.00
ihe (Interface Heater):	ON
CAD (Collisionally Activated Dissociation Gas):	4.00 (nitrogen)
EP (Entrance Potential):	-12.00

Detection Parameters (Negative)

CEM (Channel Electron Multiplier):	2600.0
DF (Deflector):	200.0

3.4. PREPARATION OF MOBILE PHASE/DILUENT

The mobile phase/diluent (2 mM ammonium acetate in 70:30 deionized water:acetonitrile) was prepared by dissolving approximately 0.154 g of ammonium acetate in 700 mL of deionized (DI) water. Acetonitrile (ACN, 300 mL) was added, and the solution was stirred to achieve complete dissolution and vacuum-degassed. The preparation was scaled as needed.

3.5. PREPARATION OF THE CALIBRATION STANDARD STOCK SOLUTION AND CALIBRATION STANDARDS

A calibration standard stock solution was prepared at a concentration of 200 µg [ ]/mL as follows. Approximately 0.0100 g of [ ] ([ ] log no. 7216A) was accurately weighed in a tared glass weigh funnel and transferred to a 50-mL volumetric flask with rinses of DI water. Additional DI water was added as needed to yield the desired concentration, and the solution was stirred to achieve complete dissolution.

An aliquot (0.5 mL) of the calibration standard stock solution was transferred to a 15-mL polypropylene tube containing 9.5 mL of mobile phase to yield a working stock solution at a concentration of 10.0 µg [ ]/mL. Dilutions of this working stock solution were prepared in mobile phase in autosampler vials to yield calibration standards spanning the concentration range of 250 to 3000 ng [ ]/mL.

3.6. PREPARATION OF QUALITY CONTROL STOCK SOLUTION

A quality control (QC) stock solution was prepared at a concentration of 5.0 mg [ ]/mL as follows. Approximately 0.126 g of [ ] log no. 7216A) was accurately weighed in a tared 25-mL volumetric flask. DI water was added as needed to yield the desired concentration, and the solution was stirred to achieve complete dissolution.

3.7. PREPARATION OF QUALITY CONTROL SAMPLES

The QC samples were prepared in triplicate. Aliquots of the QC stock solution were added to 1.0 mL of sterile water in 50-mL polypropylene tubes to achieve QC sample concentrations of 2.0 mg/mL. Appropriate volumes of mobile phase were added to each tube to achieve a final volume of 40.0 mL, and the samples were thoroughly mixed. Secondary dilutions were prepared with mobile phase in 5.0-mL polypropylene tubes. A portion of each QC sample was transferred to an amber autosampler vial for analysis.

Level	Initial Concentration (mg/mL)	Sterile Water (mL)	Stock QC Volume (mL)	Diluent Volume (mL)	Total Volume (mL)	Diluted Concentration (µg/mL)
Blank	0.0	1.0	0.0	39.0	40.0	0.0
QC	2.0	1.0	0.400	38.6	40	50.0

Secondary Dilutions

Level	Initial Concentration (mg/mL)	Aliquot Volume (mL)	Diluent Volume (mL)	Total Volume (mL)	Final Concentration (ng/mL)
Blank	0.0	0.080	3.92	4.0	0.0
QC	2.0	0.080	3.92	4.0	1000

3.8. SAMPLE PROCESSING

Formulation samples (1.0 mL) were diluted with 39.0 mL of mobile phase in 50-mL polypropylene tubes. The samples were thoroughly mixed, and a secondary dilution was prepared with mobile phase in new polypropylene tubes. A portion of each sample was transferred to an amber autosampler vial for analysis.

Group	Test Article Concentration (mg/mL)	Sample Volume (mL)	Diluent Volume (mL)	Total Volume (mL)	Diluted Concentration (µg/mL)
1	2	1.0	39.0	40.0	50

Secondary Dilutions

Group	Test Article Concentration (mg/mL)	Aliquot Volume (mL)	Diluent Volume (mL)	Total Volume (mL)	Final Concentration (ng/mL)
1	2	0.080	3.92	4.0	1000

3.9. CALIBRATION AND QUANTITATION

Single injections were made of each calibration standard and processed QC and formulation sample. A calibration curve was constructed for each set of analyses using Analyst® software. The [ ] peak areas (y) and the theoretical concentrations of the calibration standards (x) were fit to the quadratic function with $1/x^2$ weighting, excluding the origin. Concentrations were calculated using Analyst® software. The concentration

data were transferred to an Excel spreadsheet, where appropriate summary statistics, i.e., mean, standard deviation (SD), relative standard deviation (RSD), percent relative error (%RE) and percent of target, were calculated and presented in tabular form. The concentrations of the dosing formulations and QC samples were calculated by applying any necessary multiplication factors

4. RESULTS AND DISCUSSION

Under the described chromatographic conditions, the retention time of the test article was approximately 3.2 minutes. Figures 1, 2, 3 and 4 are typical chromatograms of a calibration standard, a processed QC sample, a processed formulation sample and a processed vehicle sample, respectively. The total analysis time required for each run was 5 minutes.

4.1. SPECIFICITY/SELECTIVITY

As shown in Figure 4 (and in contrast to the chromatograms shown in Figures 1 through 3), assay specificity/selectivity was confirmed when HPLC/MS/MS analysis of a processed vehicle sample revealed that there were no significant peaks at or near the retention time for the test article (approximately 3.2 minutes).

4.2. ASSAY VALIDATION: CALIBRATION REPRODUCIBILITY

During each of 4 validation sessions, triplicate calibration standards at 5 concentrations were prepared and analyzed as previously described. Single injections were made of each calibration standard. The resulting peak area versus concentration data were fit to the quadratic function with $1/x^2$ weighting, excluding the origin, using least-squares regression analysis. The results of the regression analyses were used to back-calculate the corresponding concentrations from the peak area data. The reproducibility of the calibration curve data was considered valid when 1) the inter-session variability of the back-calculated concentrations at each calibration level was $\leq$ 10% RSD, except at the lowest calibration level where $\leq$ 15% RSD was acceptable; and 2) the mean back-calculated concentrations at each calibration level were within 10% of the

theoretical values (%RE within ± 10%), except at the lowest calibration level where %RE within ± 15% was acceptable.

The back-calculated concentrations and the associated intra- and inter-session statistics for the [ ] assay calibration standards are summarized in Table 1. The inter-session variability of the back-calculated concentrations ranged from 0.95% to 2.4% RSD. The inter-session mean concentrations had %RE values ranging from -1.4% to 1.1%. Based on the stated criteria, the reproducibility of the calibration data was acceptable.

4.3. ASSAY VALIDATION: PRECISION AND ACCURACY

During each of 4 validation sessions, triplicate QC samples at a single concentration were prepared and analyzed as described previously. Single injections were made of each processed QC sample. The results of the regression analyses were used to back-calculate the corresponding concentrations from the QC peak area data. The variability (RSD) of the calculated QC concentration data was used as a measure of assay precision. The precision of the method was considered acceptable when the inter-session RSD of the calculated QC concentration was ≤ 10%. The difference between the theoretical and mean calculated QC concentration (%RE) was used as a measure of assay accuracy. The accuracy of the method was considered acceptable when the inter-session mean calculated concentration had a %RE value within ± 10%.

The calculated concentrations and the associated intra- and inter-session statistics for the [ ] calculated concentration was 5.2% RSD. The inter-session mean concentration had a %RE value of 4.2%.

Based on the stated criteria, the precision and accuracy of the [ ] assay were acceptable.

4.4. STABILITY OF PROCESSED SAMPLES

Calibration standards and processed QC samples were analyzed. The 250 and 3000 ng/mL calibration standards and the processed QC samples were then stored at room temperature for 1 day and reanalyzed to assess test article stability. The mean test article concentrations in the calibration standards and processed QC samples after storage ranged from 102% to 105% of the time-zero values (Table 3), which met the [ ] standard operating procedure (SOP) requirement for stability, i.e., the mean post-storage concentration was not less than 90% of the time-zero value.

4.5. CONCENTRATION ANALYSIS OF DOSING FORMULATIONS

The results of the determination of the test article concentration in a sterile water formulation prepared on 6 and 7 December 2006 are presented in Table 4. The concentration prior to filtration was 2.07 mg/mL (103% of target). The mean post-filtration concentration was 2.11 mg/mL (105% of target). The analyzed post-filtration [ ] formulation used for dose administration met the [ ] SOP requirement for concentration acceptability for solution formulations, i.e., the analyzed concentrations were within 90% to 110% of the target concentrations.

4.6. TEST ARTICLE STABILITY IN FORMULATIONS

The formulation prepared on 6 December 2006 and initially analyzed on 7 December 2006 was refrigerated for 5 days and reanalyzed to assess test article stability in the formulation. The 5-day stability results for the formulation are presented in Table 5. The mean post-storage concentration was 102% of the corresponding time-zero value, which met the previously stated [ ] SOP requirement for stability.

5. CONCLUSION

This report provides a detailed description of an HPLC/MS/MS method in ESI- mode for the determination of [ ] in sterile water. Method specificity/selectivity, calibration reproducibility, precision and accuracy were assessed and validated. The analyzed [ ] formulations were analyzed to assess test article concentration prior to and after filtration,

and the results met all appropriate [ ] SOP requirements. Test article stability in formulation stored refrigerated for 5 days was assessed, and the results met [ ] SOP acceptance criteria. The analyzed [ ] formulation used for dose administration met the [ ] SOP requirement for concentration acceptability for solution formulations.

TABLES 1-5

PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 1: [ ] Back-Calculated Concentrations And Intra-Session Statistics Of Calibration Standards

Theo. Conc. (ng/mL)	250	750	1000	2000	3000
Set 1 (5-6 Dec 2006), I6-534006d, analyst DKP					
Sample 1	252	752	994	1976	2999
Sample 2	252	751	1007	1971	2996
Sample 3	245	748	1013	1992	3056
Intra-set Statistics					
n	3	3	3	3	3
Mean	250	750	1005	1980	3017
SD	4.3	2.5	9.5	11	34
RSD	1.7	0.33	0.95	0.55	1.1
%RE	-0.056	0.063	0.47	-1.0	0.56
Set 2 (5-6 Dec 2006), I6-534006e, analyst DKP					
Sample 1	253	757	1012	1912	2970
Sample 2	247	739	1036	1936	3052
Sample 3	250	743	996	2037	3068
Intra-set Statistics					
n	3	3	3	3	3
Mean	250	747	1015	1962	3030
SD	2.9	9.5	20	66	53
RSD	1.2	1.3	2.0	3.4	1.7
%RE	-0.060	-0.45	1.5	-1.9	0.99
Set 3 (7 Dec 2006), I6-534006f, analyst DKP					
Sample 1	256	750	998	1953	3008
Sample 2	242	730	1019	1962	3027
Sample 3	252	757	1017	2020	3016
Intra-set Statistics					
n	3	3	3	3	3
Mean	250	746	1011	1978	3017
SD	7.3	14	12	36	9.5
RSD	2.9	1.9	1.1	1.8	0.32
%RE	-0.0027	-0.56	1.1	-1.1	0.56

PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 1: [ ] Back-Calculated Concentrations And Intra-Session Statistics Of Calibration Standards

Theo. Conc. (ng/mL)	250	750	1000	2000	3000
Set 4 (11 Dec 2006), I6-534006g, analyst DKP					
Sample 1	259	726	998	1937	3039
Sample 2	252	737	1022	1943	3006
Sample 3	238	778	1014	2035	3019
Intra-set Statistics					
n	3	3	3	3	3
Mean	250	747	1011	1972	3021
SD	11	27	12	55	17
RSD	4.3	3.7	1.2	2.8	0.56
%RE	-0.040	-0.37	1.1	-1.4	0.71
Inter-set Statistics					
n	12	12	12	12	12
Mean	250	748	1011	1973	3021
SD	5.9	14	13	41	29
RSD	2.4	1.9	1.2	2.1	0.95
%RE	-0.040	-0.33	1.1	-1.4	0.70

PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 2: [ ] Concentrations And Intra-Session Statistics Of Quality Control Samples

Theo. Conc. (mg/mL)	2.00
Set 1 (5-6 Dec 2006), I6-534006d, analyst DKP	
Sample 1	2.00
Sample 2	2.04
Sample 3	2.03
Intra-set Statistics	
n	3
Mean	2.02
SD	0.024
RSD	1.2
%RE	1.2
Set 2 (5-6 Dec 2006), I6-534006e, analyst DKP	
Sample 1	2.24
Sample 2	2.28
Sample 3	2.27
Intra-set Statistics	
n	3
Mean	2.26
SD	0.024
RSD	1.1
%RE	13
Set 3 (7 Dec 2006), I6-534006f, analyst DKP	
Sample 1	2.03
Sample 2	2.04
Sample 3	2.02
Intra-set Statistics	
n	3
Mean	2.03
SD	0.0094
RSD	0.46
%RE	1.5

PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 3: Room Temperature Stability Of [ ] In Processed Samples

Storage Duration (Days)	Theo. Conc. (ng/mL)	Run # (534006-)	Ref. # (534006-)	Analyzed Conc. (ng/mL)	% Target	Mean Conc (ng/mL)	RSD (%)	Mean % Target	% of Time Zero
0	250	69	8-2	252	101	250	1.7	99.9	NA
		70	8-3	252	101				
		71	8-4	245	98.0				
	3000	81	8-14	2999	100	3017	1.1	101	NA
		82	8-15	2996	99.9				
		83	8-16	3056	102				
1	250	138	8-2	260	104	261	0.83	104	**104**
		139	8-3	263	105				
		140	8-4	259	104				
	3000	144	8-14	3177	106	3177	1.3	106	**105**
		145	8-15	3137	105				
		146	8-16	3217	107				

Storage Duration (Days)	Theo. Conc. (mg/mL)	Run # (534006-)	Ref. # (534006-)	Analyzed Conc. (mg/mL)	% Target	Mean Conc (mg/mL)	RSD (%)	Mean % Target	% of Time Zero
0	2.0	85	9-7	2.00	99.8	2.02	1.2	101	NA
		86	9-8	2.04	102				
		87	9-9	2.03	102				
1	2.0	141	9-7	2.04	102	2.06	1.1	103	**102**
		142	9-8	2.08	104				
		143	9-9	2.07	103				

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PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 4: Concentration Analysis Of The 6 And 7 December 2006 Formulation

(Analyzed 07 December 2006)

Dose Conc (mg/mL)	Group	Ref # (534006 -)	Run # (534006)	Analyzed Conc (mg/mL)	Percent of Target (%)	Mean Conc (mg/mL)	SD	RSD (%)	Mean Conc % of Target (%)
Concentration of dosing preparations prior to filtration									
2	1	17 - 5	133	2.44	122	2.25	0.27	12	113
		17 - 6	134	2.07	103				
Concentration of dosing preparations after filtration									
2	1	17 - 7	135	2.09	105	2.11	0.021	0.99	105
		17 - 8	136	2.12	106				

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PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 5: 5-Day Refrigerated Stability Analysis Of The 6 And 7 December 2006 Formulation
(Analyzed 11-12 Dec 2006)

Group	Dose Conc. (mg/mL)	Ref # (534006 -)	Run #	Analyzed Conc. (mg/mL)	Percent of Target (%)	Mean Conc. (mg/mL)	SD	RSD (%)	Mean Conc % of Target (%)	Percent of Time Zero (%)
1	2	24 - 3	173	2.16	108	2.15	0.025	1.2	107	102
		24 - 4	174	2.13	106					

Time Zero Concentration:	Group	(mg/mL)
	1	2.11

534006 report tables.xls 5dysb
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534006

ATTACHMENT I

Supporting Data

Table A-1: I6-534006d Data

Note:
Validation Session 1
QC samples are listed as the diluted concentration of QC 1000.

Results Path: D:\SciexData\Projects\534006\Dosing\Results\I6-534006d.rdb
Results Name: I6-534006d.rdb

	File Name	Sample ID	Sample Name	Sample Type	Analyte Peak Name	Use Record	Analyte Concentration (ng/mL)	Dilution Factor
1	I6-534006d\0066.wiff	8-2	system suit	Unknown			N/A	1.00
2	I6-534006d\0067.wiff	8-2	system suit	Unknown			N/A	1.00
3	I6-534006d\0068.wiff	8-2	system suit	Unknown			N/A	1.00
4	I6-534006d\0069.wiff	8-2	C 250	Standard		☒	250.00	1.00
5	I6-534006d\0070.wiff	8-3	C 250	Standard		☒	250.00	1.00
6	I6-534006d\0071.wiff	8-4	C 250	Standard		☒	250.00	1.00
7	I6-534006d\0072.wiff	8-5	C 750	Standard		☒	750.00	1.00
8	I6-534006d\0073.wiff	8-6	C 750	Standard		☒	750.00	1.00
9	I6-534006d\0074.wiff	8-7	C 750	Standard		☒	750.00	1.00
10	I6-534006d\0075.wiff	8-8	C 1000	Standard		☒	1000.0	1.00
11	I6-534006d\0076.wiff	8-9	C 1000	Standard		☒	1000.0	1.00
12	I6-534006d\0077.wiff	8-10	C 1000	Standard		☒	1000.0	1.00
13	I6-534006d\0078.wiff	8-11	C 2000	Standard		☒	2000.0	1.00
14	I6-534006d\0079.wiff	8-12	C 2000	Standard		☒	2000.0	1.00
15	I6-534006d\0080.wiff	8-13	C 2000	Standard		☒	2000.0	1.00
16	I6-534006d\0081.wiff	8-14	C 3000	Standard		☒	3000.0	1.00
17	I6-534006d\0082.wiff	8-15	C 3000	Standard		☒	3000.0	1.00
18	I6-534006d\0083.wiff	8-16	C 3000	Standard		☒	3000.0	1.00
19	I6-534006d\0084.wiff	9-6	QC 0	Quality Control		☒	0.0000	1.00
20	I6-534006d\0085.wiff	9-7	QC 1000	Quality Control		☒	1000.0	1.00
21	I6-534006d\0086.wiff	9-8	QC 1000	Quality Control		☒	1000.0	1.00
22	I6-534006d\0087.wiff	9-9	QC 1000	Quality Control		☒	1000.0	1.00

Printing Date: Thursday, December 07, 2006
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Operator: ullman
Analyst Version: 1.4.1

Results Path: D:\SciexData\Projects\534006\Dosing\Results\I6-534006d.rdb
Results Name: I6-534006d.rdb

	File Name	Calculated Concentration (ng/mL)	%RE	Analyte Peak Area (counts)	Analyte Retention Time (min)	Analyte Integration Type	Record Modified	Sample Annotation
1	I6-534006d\0066.wiff	251.19	N/A	6.42e+005	3.13	Base To Base	☐	
2	I6-534006d\0067.wiff	243.65	N/A	6.25e+005	3.18	Base To Base	☐	
3	I6-534006d\0068.wiff	247.06	N/A	6.32e+005	3.17	Base To Base	☐	
4	I6-534006d\0069.wiff	252.25	0.90	6.44e+005	3.14	Base To Base	☐	
5	I6-534006d\0070.wiff	252.41	0.96	6.44e+005	3.16	Base To Base	☐	
6	I6-534006d\0071.wiff	244.92	-2.0	6.28e+005	3.16	Base To Base	☐	
7	I6-534006d\0072.wiff	752.43	0.32	1.73e+006	3.14	Base To Base	☐	
8	I6-534006d\0073.wiff	751.32	0.18	1.73e+006	3.16	Base To Base	☐	
9	I6-534006d\0074.wiff	747.66	-0.31	1.72e+006	3.13	Base To Base	☐	
10	I6-534006d\0075.wiff	994.10	-0.59	2.24e+006	3.14	Base To Base	☐	
11	I6-534006d\0076.wiff	1007.3	0.73	2.27e+006	3.12	Base To Base	☐	
12	I6-534006d\0077.wiff	1012.6	1.3	2.28e+006	3.13	Base To Base	☐	
13	I6-534006d\0078.wiff	1976.0	-1.2	4.16e+006	3.11	Base To Base	☐	
14	I6-534006d\0079.wiff	1971.1	-1.4	4.15e+006	3.14	Base To Base	☐	
15	I6-534006d\0080.wiff	1991.8	-0.41	4.19e+006	3.15	Base To Base	☐	
16	I6-534006d\0081.wiff	2999.1	-0.029	5.93e+006	3.13	Base To Base	☐	
17	I6-534006d\0082.wiff	2995.5	-0.15	5.93e+006	3.13	Base To Base	☐	
18	I6-534006d\0083.wiff	3056.0	1.9	6.03e+006	3.10	Base To Base	☐	
19	I6-534006d\0084.wiff	No Peak	0.0	0.00e+000	0.00	No Peak	☒	percent noise change
20	I6-534006d\0085.wiff	998.37	-0.16	2.25e+006	3.14	Base To Base	☐	
21	I6-534006d\0086.wiff	1021.3	2.1	2.29e+006	3.09	Base To Base	☐	
22	I6-534006d\0087.wiff	1017.2	1.7	2.29e+006	3.10	Base To Base	☐	

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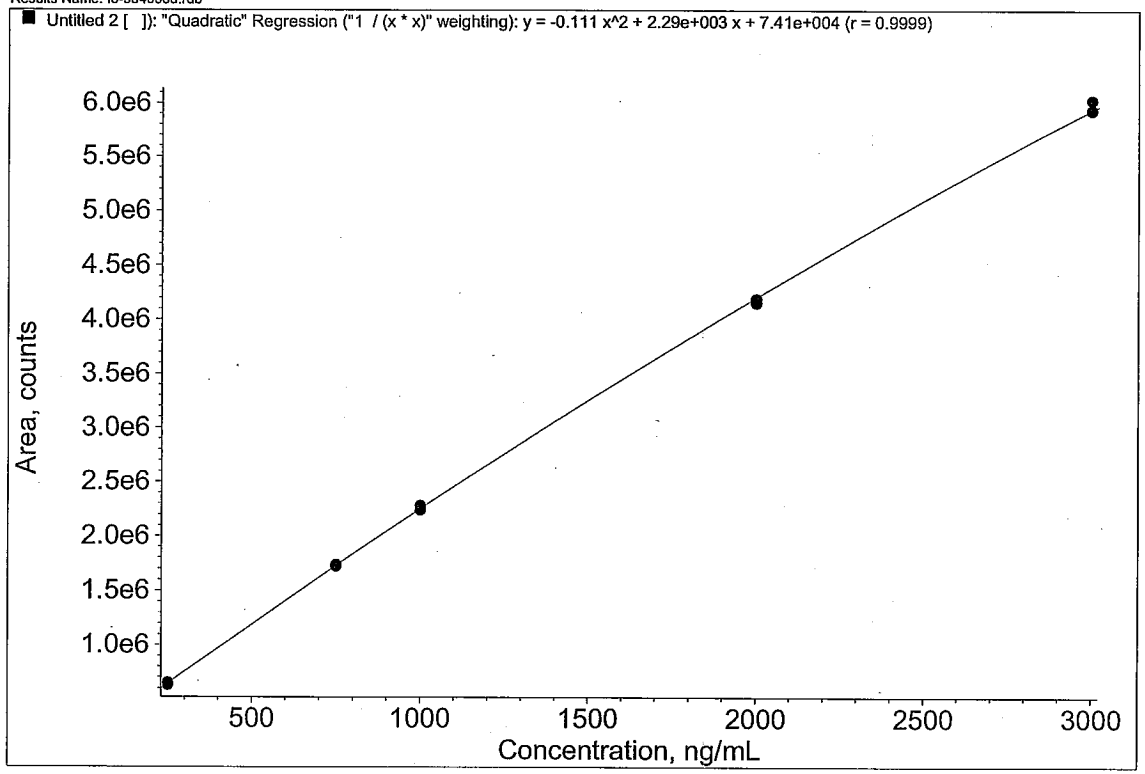
Operator: ullman
Analyst Version: 1.4.1

Results Path: D:\SciexData\Projects\534006\Dosing\Results\I6-534006d.rdb
Results Name: I6-534006d.rdb



Printing Date: Thursday, December 07, 2006
Printing Time: 9:19:29 AM

Operator: ullman
Analyst Version: 1.4.1

Table A-2: 16-534006e Data

Note:
Validation Session II
QC samples are listed as the diluted concentration of QC 1000.

Results Path: D:\SciexData\Projects\534006\Dosing\Results\I6-534006e.rdb
Results Name: I6-534006e.rdb

	File Name	Sample ID	Sample Name	Sample Type	Analyte Peak Name	Use Record	Analyte Concentration (ng/mL)	Dilution Factor	Calculated Concentration (ng/mL)
1	I6-534006e\0088.wiff	6-1	Diluent	Unknown			N/A	1.00	No Peak
2	I6-534006e\0089.wiff	11-2	C 250	Standard		☒	250.00	1.00	252.80
3	I6-534006e\0090.wiff	11-3	C 250	Standard		☒	250.00	1.00	247.04
4	I6-534006e\0091.wiff	11-4	C 250	Standard		☒	250.00	1.00	249.71
5	I6-534006e\0092.wiff	11-5	C 750	Standard		☒	750.00	1.00	757.33
6	I6-534006e\0093.wiff	11-6	C 750	Standard		☒	750.00	1.00	739.40
7	I6-534006e\0094.wiff	11-7	C 750	Standard		☒	750.00	1.00	743.18
8	I6-534006e\0095.wiff	11-8	C 1000	Standard		☒	1000.0	1.00	1011.8
9	I6-534006e\0096.wiff	11-9	C 1000	Standard		☒	1000.0	1.00	1036.3
10	I6-534006e\0097.wiff	11-10	C 1000	Standard		☒	1000.0	1.00	996.03
11	I6-534006e\0098.wiff	11-11	C 2000	Standard		☒	2000.0	1.00	1911.9
12	I6-534006e\0099.wiff	11-12	C 2000	Standard		☒	2000.0	1.00	1936.3
13	I6-534006e\0100.wiff	11-13	C 2000	Standard		☒	2000.0	1.00	2037.0
14	I6-534006e\0101.wiff	11-14	C 3000	Standard		☒	3000.0	1.00	2969.5
15	I6-534006e\0102.wiff	11-15	C 3000	Standard		☒	3000.0	1.00	3051.5
16	I6-534006e\0103.wiff	11-16	C 3000	Standard		☒	3000.0	1.00	3068.2
17	I6-534006e\0104.wiff	12-6	QC 0	Quality Control		☒	0.0000	1.00	No Peak
18	I6-534006e\0105.wiff	12-7	QC 1000	Quality Control		☒	1000.0	1.00	1117.6
19	I6-534006e\0106.wiff	12-8	QC 1000	Quality Control		☒	1000.0	1.00	1141.2
20	I6-534006e\0107.wiff	12-9	QC 1000	Quality Control		☒	1000.0	1.00	1134.7

Printing Date: Thursday, December 07, 2006
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Operator: ullman
Analyst Version: 1.4.1

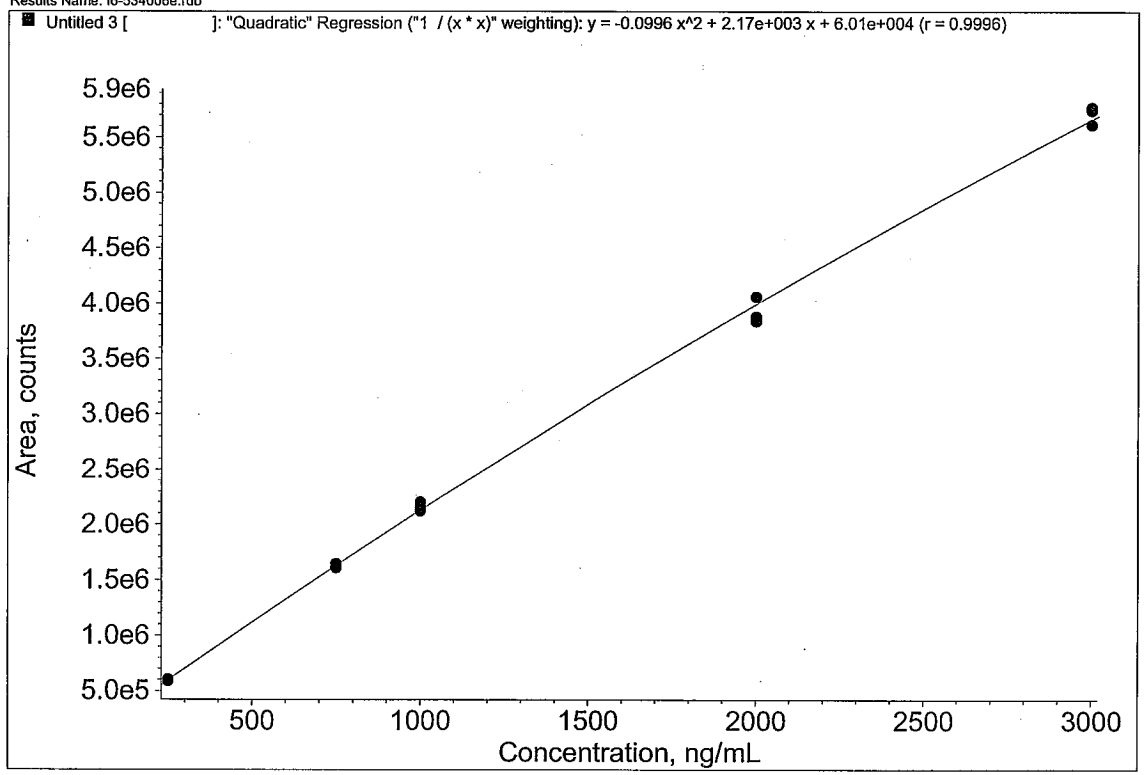
Results Path: D:\SciexData\Projects\534006\Dosing\Results\I6-534006e.rdb
Results Name: I6-534006e.rdb

	File Name	%RE	Analyte Peak Area (counts)	Analyte Retention Time (min)	Analyte Integration Type	Record Modified	Sample Annotation
1	I6-534006e\0088.wiff	N/A	0.00e+000	0.00	No Peak	☒	percent noise change
2	I6-534006e\0089.wiff	1.1	6.01e+005	3.11	Base To Base	☐	
3	I6-534006e\0090.wiff	-1.2	5.89e+005	3.12	Base To Base	☐	
4	I6-534006e\0091.wiff	-0.11	5.95e+005	3.10	Base To Base	☐	
5	I6-534006e\0092.wiff	0.98	1.64e+006	3.10	Base To Base	☐	
6	I6-534006e\0093.wiff	-1.4	1.61e+006	3.11	Base To Base	☐	
7	I6-534006e\0094.wiff	-0.91	1.61e+006	3.11	Base To Base	☐	
8	I6-534006e\0095.wiff	1.2	2.15e+006	3.12	Base To Base	☐	
9	I6-534006e\0096.wiff	3.6	2.20e+006	3.10	Base To Base	☐	
10	I6-534006e\0097.wiff	-0.40	2.12e+006	3.10	Base To Base	☐	
11	I6-534006e\0098.wiff	-4.4	3.84e+006	3.11	Base To Base	☐	
12	I6-534006e\0099.wiff	-3.2	3.88e+006	3.10	Base To Base	☐	
13	I6-534006e\0100.wiff	1.8	4.06e+006	3.11	Base To Base	☐	
14	I6-534006e\0101.wiff	-1.0	5.61e+006	3.10	Valley	☐	
15	I6-534006e\0102.wiff	1.7	5.74e+006	3.08	Base To Base	☐	
16	I6-534006e\0103.wiff	2.3	5.77e+006	3.11	Base To Base	☐	
17	I6-534006e\0104.wiff	0.0	0.00e+000	0.00	No Peak	☒	noise percent change
18	I6-534006e\0105.wiff	12.	2.36e+006	3.10	Base To Base	☐	
19	I6-534006e\0106.wiff	14.	2.40e+006	3.09	Base To Base	☐	
20	I6-534006e\0107.wiff	13.	2.39e+006	3.10	Base To Base	☐	

Printing Date: Thursday, December 07, 2006
Printing Time: 9:35:03 AM

Operator: ullman
Analyst Version: 1.4.1

Results Path: D:\SciexData\Projects\534006\Dosing\Results\I6-534006e.rdb
Results Name: I6-534006e.rdb



Printing Date: Thursday, December 07, 2006
Printing Time: 9:35:42 AM

Operator: ullman
Analyst Version: 1.4.1

Table A-3: I6-534006f Data

Note:
Validation Session III
QC samples are listed as the diluted concentration of QC 1000.

Results Path: D:\SciexData\Projects\534006\Dosing\Results\I6-534006f.rdb
Results Name: I6-534006f.rdb

	File Name	Sample ID	Sample Name	Sample Type	Analyte Peak Name	Use Record	Analyte Concentration (ng/mL)	Dilution Factor	Calculated Concentration (ng/mL)
1	I6-534006f\0108.wiff	15-2	system suit	Unknown			N/A	1.00	214.62
2	I6-534006f\0109.wiff	15-2	system suit	Unknown			N/A	1.00	222.06
3	I6-534006f\0110.wiff	15-2	system suit	Unknown			N/A	1.00	239.86
4	I6-534006f\0111.wiff	na	mobile phase	Unknown			N/A	1.00	No Peak
5	I6-534006f\0112.wiff	15-2	C 250	Standard		☒	250.00	1.00	256.01
6	I6-534006f\0113.wiff	15-3	C 250	Standard		☒	250.00	1.00	241.89
7	I6-534006f\0114.wiff	15-4	C 250	Standard		☒	250.00	1.00	252.08
8	I6-534006f\0115.wiff	15-5	C 750	Standard		☒	750.00	1.00	749.77
9	I6-534006f\0116.wiff	15-6	C 750	Standard		☒	750.00	1.00	730.09
10	I6-534006f\0117.wiff	15-7	C 750	Standard		☒	750.00	1.00	757.49
11	I6-534006f\0118.wiff	15-8	C 1000	Standard		☒	1000.0	1.00	997.99
12	I6-534006f\0119.wiff	15-9	C 1000	Standard		☒	1000.0	1.00	1018.6
13	I6-534006f\0120.wiff	15-10	C 1000	Standard		☒	1000.0	1.00	1017.2
14	I6-534006f\0121.wiff	15-11	C 2000	Standard		☒	2000.0	1.00	1952.9
15	I6-534006f\0122.wiff	15-12	C 2000	Standard		☒	2000.0	1.00	1962.0
16	I6-534006f\0123.wiff	15-13	C 2000	Standard		☒	2000.0	1.00	2020.1
17	I6-534006f\0124.wiff	15-14	C 3000	Standard		☒	3000.0	1.00	3007.7
18	I6-534006f\0125.wiff	15-15	C 3000	Standard		☒	3000.0	1.00	3026.7
19	I6-534006f\0126.wiff	15-16	C 3000	Standard		☒	3000.0	1.00	3015.6
20	I6-534006f\0127.wiff	na	mobile phase	Unknown			N/A	1.00	No Peak
21	I6-534006f\0128.wiff	16-6	QC 0	Quality Control		☒	0.0000	1.00	No Peak
22	I6-534006f\0129.wiff	16-7	QC 1000	Quality Control		☒	1000.0	1.00	1015.4
23	I6-534006f\0130.wiff	16-8	QC 1000	Quality Control		☒	1000.0	1.00	1019.4
24	I6-534006f\0131.wiff	16-9	QC 1000	Quality Control		☒	1000.0	1.00	1010.0
25	I6-534006f\0132.wiff	na	mobile phase	Unknown			N/A	1.00	No Peak

Printing Date: Friday, December 08, 2006
Printing Time: 9:12:49 AM

Operator: ullman
Analyst Version: 1.4.1

Results Path: D:\SciexData\Projects\534006\Dosing\Results\I6-534006f.rdb
Results Name: I6-534006f.rdb

	File Name	Sample ID	Sample Name	Sample Type	Analyte Peak Name	Use Record	Analyte Concentration (ng/mL)	Dilution Factor	Calculated Concentration (ng/mL)
26	I6-534006f\0133.wiff	17-5	group	Unknown			N/A	1.00	1220.1
27	I6-534006f\0134.wiff	17-6	group	Unknown			N/A	1.00	1032.7
28	I6-534006f\0135.wiff	17-7	group	Unknown			N/A	1.00	1045.7
29	I6-534006f\0136.wiff	17-8	group	Unknown			N/A	1.00	1060.5
30	I6-534006f\0137.wiff	na	mobile phase	Unknown			N/A	1.00	No Peak
31	I6-534006f\0138.wiff	8-2	C 250 PSS	Unknown			N/A	1.00	259.95
32	I6-534006f\0139.wiff	8-3	C 250 PSS	Unknown			N/A	1.00	263.09
33	I6-534006f\0140.wiff	8-4	C 250 PSS	Unknown			N/A	1.00	258.95
34	I6-534006f\0141.wiff	9-7	QC 1000 PSS	Unknown			N/A	1.00	1019.2
35	I6-534006f\0142.wiff	9-8	QC 1000 PSS	Unknown			N/A	1.00	1040.2
36	I6-534006f\0143.wiff	9-9	QC 1000 PSS	Unknown			N/A	1.00	1034.7
37	I6-534006f\0144.wiff	8-14	C 3000 PSS	Unknown			N/A	1.00	3176.8
38	I6-534006f\0145.wiff	8-15	C 3000 PSS	Unknown			N/A	1.00	3137.0
39	I6-534006f\0146.wiff	8-16	C 3000 PSS	Unknown			N/A	1.00	3217.3
40	I6-534006f\0147.wiff	na	mobile phase	Unknown			N/A	1.00	No Peak

Printing Date: Friday, December 08, 2006
Printing Time: 9:12:49 AM

Operator: ullman
Analyst Version: 1.4.1

Results Path: D:\SciexData\Projects\534006\Dosing\Results\I6-534006f.rdb
Results Name: I6-534006f.rdb

	File Name	%RE	Analyte Peak Area (counts)	Analyte Retention Time (min)	Analyte Integration Type	Record Modified	Sample Annotation
1	I6-534006f\0108.wiff	N/A	6.12e+005	3.39	Base To Base	☒	RT & peak split change
2	I6-534006f\0109.wiff	N/A	6.30e+005	3.30	Base To Base	☐	
3	I6-534006f\0110.wiff	N/A	6.74e+005	3.28	Base To Base	☐	
4	I6-534006f\0111.wiff	N/A	0.00e+000	0.00	No Peak	☒	percent noise
5	I6-534006f\0112.wiff	2.4	7.13e+005	3.30	Base To Base	☐	
6	I6-534006f\0113.wiff	-3.2	6.79e+005	3.27	Base To Base	☐	
7	I6-534006f\0114.wiff	0.83	7.03e+005	3.27	Base To Base	☐	
8	I6-534006f\0115.wiff	-0.031	1.87e+006	3.24	Base To Base	☐	
9	I6-534006f\0116.wiff	-2.7	1.82e+006	3.24	Base To Base	☐	
10	I6-534006f\0117.wiff	1.0	1.89e+006	3.24	Base To Base	☐	
11	I6-534006f\0118.wiff	-0.20	2.42e+006	3.26	Base To Base	☐	
12	I6-534006f\0119.wiff	1.9	2.46e+006	3.24	Base To Base	☐	
13	I6-534006f\0120.wiff	1.7	2.46e+006	3.23	Base To Base	☐	
14	I6-534006f\0121.wiff	-2.4	4.35e+006	3.23	Base To Base	☐	
15	I6-534006f\0122.wiff	-1.9	4.37e+006	3.21	Base To Base	☐	
16	I6-534006f\0123.wiff	1.0	4.48e+006	3.22	Base To Base	☒	peak split
17	I6-534006f\0124.wiff	0.26	6.15e+006	3.22	Base To Base	☐	
18	I6-534006f\0125.wiff	0.89	6.18e+006	3.21	Base To Base	☐	
19	I6-534006f\0126.wiff	0.52	6.16e+006	3.22	Base To Base	☐	
20	I6-534006f\0127.wiff	N/A	0.00e+000	0.00	No Peak	☒	percent noise
21	I6-534006f\0128.wiff	0.0	0.00e+000	0.00	No Peak	☒	percent noise
22	I6-534006f\0129.wiff	1.5	2.46e+006	3.23	Base To Base	☐	
23	I6-534006f\0130.wiff	1.9	2.47e+006	3.22	Base To Base	☐	
24	I6-534006f\0131.wiff	1.0	2.45e+006	3.20	Base To Base	☐	
25	I6-534006f\0132.wiff	N/A	0.00e+000	0.00	No Peak	☒	percent noise

Printing Date: Friday, December 08, 2006
Printing Time: 9:12:49 AM

Operator: ullman
Analyst Version: 1.4.1

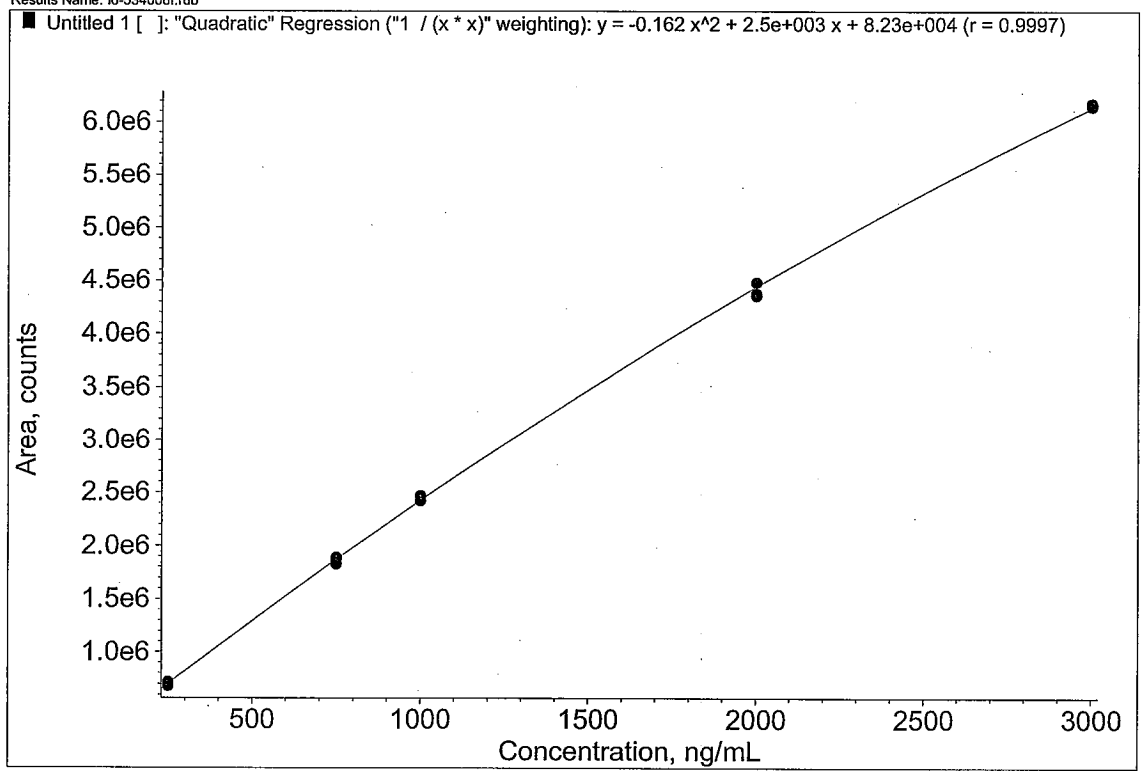
Results Path: D:\SciexData\Projects\534006\Dosing\Results\I6-534006f.rdb
Results Name: I6-534006f.rdb

	File Name	%RE	Analyte Peak Area (counts)	Analyte Retention Time (min)	Analyte Integration Type	Record Modified	Sample Annotation
26	I6-534006f\0133.wiff	N/A	2.90e+006	3.22	Base To Base	☐	
27	I6-534006f\0134.wiff	N/A	2.50e+006	3.21	Base To Base	☐	
28	I6-534006f\0135.wiff	N/A	2.52e+006	3.21	Base To Base	☐	
29	I6-534006f\0136.wiff	N/A	2.56e+006	3.18	Base To Base	☐	
30	I6-534006f\0137.wiff	N/A	0.00e+000	0.00	No Peak	☒	percent noise
31	I6-534006f\0138.wiff	N/A	7.22e+005	3.17	Base To Base	☐	
32	I6-534006f\0139.wiff	N/A	7.30e+005	3.22	Base To Base	☐	
33	I6-534006f\0140.wiff	N/A	7.20e+005	3.17	Base To Base	☐	
34	I6-534006f\0141.wiff	N/A	2.47e+006	3.20	Valley	☐	
35	I6-534006f\0142.wiff	N/A	2.51e+006	3.21	Base To Base	☐	
36	I6-534006f\0143.wiff	N/A	2.50e+006	3.18	Base To Base	☐	
37	I6-534006f\0144.wiff	N/A	6.40e+006	3.16	Base To Base	☐	
38	I6-534006f\0145.wiff	N/A	6.34e+006	3.18	Valley	☐	
39	I6-534006f\0146.wiff	N/A	6.46e+006	3.19	Base To Base	☐	
40	I6-534006f\0147.wiff	N/A	0.00e+000	0.00	No Peak	☒	percent noise

Printing Date: Friday, December 08, 2006
Printing Time: 9:12:49 AM

Operator: ullman
Analyst Version: 1.4.1

Results Path: D:\SciexData\Projects\534006\Dosing\Results\I6-534006f.rdb
Results Name: I6-534006f.rdb



Printing Date: Friday, December 08, 2006
Printing Time: 9:15:45 AM

Operator: ullman
Analyst Version: 1.4.1

Table A-4: I6-534006g Data

Note:
Validation Session IV
QC samples are listed as the diluted concentration of QC 1000.

Results Path: D:\SciexData\Projects\534006\Dosing\Results\I6-534006g.rdb
Results Name: I6-534006g.rdb

	File Name	Sample ID	Sample Name	Sample Type	Analyte Peak Name	Use Record	Analyte Concentration (ng/mL)	Dilution Factor
1	I6-534006g\0148.wiff	22-2	system suit	Unknown			N/A	1.00
2	I6-534006g\0149.wiff	22-2	system suit	Unknown			N/A	1.00
3	I6-534006g\0150.wiff	22-2	system suit	Unknown			N/A	1.00
4	I6-534006g\0151.wiff	na	mobile phase	Unknown			N/A	1.00
5	I6-534006g\0152.wiff	22-2	C 250	Standard		☒	250.00	1.00
6	I6-534006g\0153.wiff	22-3	C 250	Standard		☒	250.00	1.00
7	I6-534006g\0154.wiff	22-4	C 250	Standard		☒	250.00	1.00
8	I6-534006g\0155.wiff	22-5	C 750	Standard		☒	750.00	1.00
9	I6-534006g\0156.wiff	22-6	C 750	Standard		☒	750.00	1.00
10	I6-534006g\0157.wiff	22-7	C 750	Standard		☒	750.00	1.00
11	I6-534006g\0158.wiff	22-8	C 1000	Standard		☒	1000.0	1.00
12	I6-534006g\0159.wiff	22-9	C 1000	Standard		☒	1000.0	1.00
13	I6-534006g\0160.wiff	22-10	C 1000	Standard		☒	1000.0	1.00
14	I6-534006g\0161.wiff	22-11	C 2000	Standard		☒	2000.0	1.00
15	I6-534006g\0162.wiff	22-12	C 2000	Standard		☒	2000.0	1.00
16	I6-534006g\0163.wiff	22-13	C 2000	Standard		☒	2000.0	1.00
17	I6-534006g\0164.wiff	22-14	C 3000	Standard		☒	3000.0	1.00
18	I6-534006g\0165.wiff	22-15	C 3000	Standard		☒	3000.0	1.00
19	I6-534006g\0166.wiff	22-16	C 3000	Standard		☒	3000.0	1.00
20	I6-534006g\0167.wiff	na	mobile phase	Unknown			N/A	1.00
21	I6-534006g\0168.wiff	23-6	QC 0	Quality Control		☒	0.0000	1.00
22	I6-534006g\0169.wiff	23-7	QC 1000	Quality Control		☒	1000.0	1.00
23	I6-534006g\0170.wiff	23-8	QC 1000	Quality Control		☒	1000.0	1.00
24	I6-534006g\0171.wiff	23-9	QC 1000	Quality Control		☒	1000.0	1.00
25	I6-534006g\0172.wiff	na	mobile phase	Unknown			N/A	1.00

Printing Date: Tuesday, December 12, 2006
Printing Time: 12:57:08 PM

Operator: ullman
Analyst Version: 1.4.1

Results Path: D:\SciexData\Projects\534006\Dosing\Results\I6-534006g.rdb
Results Name: I6-534006g.rdb

	File Name	Sample ID	Sample Name	Sample Type	Analyte Peak Name	Use Record	Analyte Concentration (ng/mL)	Dilution Factor
26	I6-534006g\0173.wiff	24-3	group	Unknown			N/A	1.00
27	I6-534006g\0174.wiff	24-4	group	Unknown			N/A	1.00
28	I6-534006g\0175.wiff	na	mobile phase	Unknown			N/A	1.00

Printing Date: Tuesday, December 12, 2006
Printing Time: 12:57:08 PM

Operator: ullman
Analyst Version: 1.4.1

Results Path: D:\SciexData\Projects\534006\Dosing\Results\I6-534006g.rdb
Results Name: I6-534006g.rdb

	File Name	Calculated Concentration (ng/mL)	%RE	Analyte Peak Area (counts)	Analyte Retention Time (min)	Analyte Integration Type	Record Modified	Sample Annotation
1	I6-534006g\0148.wiff	240.60	N/A	5.58e+005	4.08	Base To Base	☐	
2	I6-534006g\0149.wiff	271.92	N/A	6.15e+005	4.08	Base To Base	☐	
3	I6-534006g\0150.wiff	260.12	N/A	5.94e+005	4.03	Base To Base	☐	
4	I6-534006g\0151.wiff	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
5	I6-534006g\0152.wiff	259.47	3.8	5.92e+005	4.11	Base To Base	☐	
6	I6-534006g\0153.wiff	251.90	0.76	5.78e+005	4.10	Base To Base	☐	
7	I6-534006g\0154.wiff	238.33	-4.7	5.53e+005	4.10	Valley	☐	
8	I6-534006g\0155.wiff	726.42	-3.1	1.43e+006	4.10	Base To Base	☐	
9	I6-534006g\0156.wiff	737.07	-1.7	1.45e+006	4.08	Base To Base	☐	
10	I6-534006g\0157.wiff	778.23	3.8	1.53e+006	4.08	Base To Base	☐	
11	I6-534006g\0158.wiff	997.70	-0.23	1.91e+006	4.10	Base To Base	☐	
12	I6-534006g\0159.wiff	1022.0	2.2	1.95e+006	4.09	Base To Base	☐	
13	I6-534006g\0160.wiff	1014.4	1.4	1.94e+006	4.05	Base To Base	☐	
14	I6-534006g\0161.wiff	1937.1	-3.1	3.46e+006	4.08	Base To Base	☐	
15	I6-534006g\0162.wiff	1943.0	-2.9	3.47e+006	4.09	Base To Base	☐	
16	I6-534006g\0163.wiff	2034.9	1.7	3.62e+006	4.08	Base To Base	☐	
17	I6-534006g\0164.wiff	3039.3	1.3	5.11e+006	4.04	Base To Base	☐	
18	I6-534006g\0165.wiff	3005.5	0.18	5.06e+006	4.10	Base To Base	☐	
19	I6-534006g\0166.wiff	3019.2	0.64	5.08e+006	4.07	Base To Base	☐	
20	I6-534006g\0167.wiff	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
21	I6-534006g\0168.wiff	No Peak	0.0	0.00e+000	0.00	No Peak	☐	
22	I6-534006g\0169.wiff	1002.3	0.23	1.92e+006	4.03	Base To Base	☐	
23	I6-534006g\0170.wiff	1019.7	2.0	1.95e+006	4.08	Base To Base	☐	
24	I6-534006g\0171.wiff	1003.5	0.35	1.92e+006	4.05	Base To Base	☐	
25	I6-534006g\0172.wiff	No Peak	N/A	0.00e+000	0.00	No Peak	☐	

Printing Date: Tuesday, December 12, 2006
Printing Time: 12:57:08 PM

Operator: ullman
Analyst Version: 1.4.1

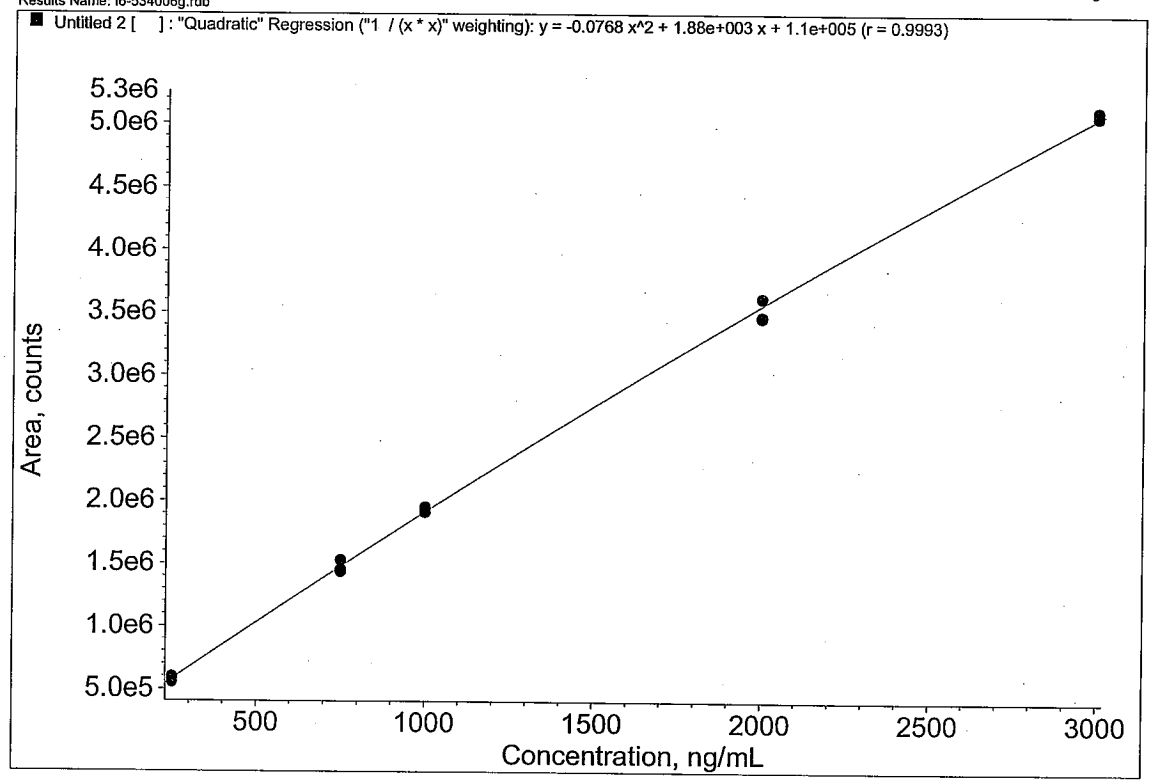
Results Path: D:\SciexData\Projects\534006\Dosing\Results\I6-534006g.rdb
Results Name: I6-534006g.rdb

	File Name	Calculated Concentration (ng/mL)	%RE	Analyte Peak Area (counts)	Analyte Retention Time (min)	Analyte Integration Type	Record Modified	Sample Annotation
26	I6-534006g\0173.wiff	1081.3	N/A	2.05e+006	4.05	Valley	☐	
27	I6-534006g\0174.wiff	1063.8	N/A	2.02e+006	4.09	Base To Base	☐	
28	I6-534006g\0175.wiff	No Peak	N/A	0.00e+000	0.00	No Peak	☐	

Printing Date: Tuesday, December 12, 2006
Printing Time: 12:57:08 PM

Operator: ullman
Analyst Version: 1.4.1

Results Path: D:\SciexData\Projects\534006\Dosing\Results\I6-534006g.rdb
Results Name: I6-534006g.rdb



Printing Date: Tuesday, December 12, 2006
Printing Time: 1:08:09 PM

Operator: ullman
Analyst Version: 1.4.1

APPENDIX C

Pretest Clinical Observations

PROJECT NO.:534006P

A PHARMACOKINETIC AND EXCRETION STUDY IN RATS
SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

----- M A L E -----

TABLE RANGE:	12-01-06 TO 12-11-06
GROUP:	1
NORMAL	
-NO SIGNIFICANT CLINICAL OBSERVATIONS	29/15
EXCRETA	
-SOFT FECES	1/ 1

1- PRETEST

----- F E M A L E -----

TABLE RANGE: 12-01-06 TO 12-11-06
GROUP: 1

NORMAL
-NO SIGNIFICANT CLINICAL OBSERVATIONS 30/15

1- PRETEST

APPENDIX D

Animal Room Environmental Conditions

PROJECT NO. 534006

A PHARMACOKINETIC AND EXCRETION STUDY IN RATS
TEMPERATURE/HUMIDITY - DAILY SUMMARY REPORT BY STUDY

STUDY SPECIFICATIONS: 534006

DATE IN: 11/28/06 TIME IN: 7:00
DATE OUT: 12/13/06 TIME OUT: 16:00

ROOM SPECIFICATIONS: B ROOM 127
SPECIES: RAT

LOW TEMPERATURE °F: 66.0 HIGH TEMPERATURE °F: 76.0 LOW HUMIDITY: 30.0
LOW TEMPERATURE °C: 18.9 HIGH TEMPERATURE °C: 24.4 HIGH HUMIDITY: 70.0

	TEMPERATURE		HUMIDITY
DATE	MEAN (°F)	MEAN (°C)	MEAN (%RH)
28-Nov-06	70.6	21.4	33.6
29-Nov-06	70.5	21.4	45.9
30-Nov-06	70.5	21.4	44.5
01-Dec-06	70.4	21.3	31.6
02-Dec-06	70.5	21.4	29.3 -
03-Dec-06	70.5	21.4	37.2
04-Dec-06	70.4	21.4	36.2
05-Dec-06	70.5	21.4	37.4
06-Dec-06	70.5	21.4	39.4
07-Dec-06	70.5	21.4	35.2
08-Dec-06	70.2	21.2	36.4
09-Dec-06	70.5	21.4	34.3
10-Dec-06	70.5	21.4	36.9
11-Dec-06	70.6	21.4	38.2
12-Dec-06	70.4	21.4	41.6
13-Dec-06	70.5	21.4	43.2

NOTE: + = VALUE WAS GREATER THAN HIGH RANGE
- = VALUE WAS LESS THAN LOW RANGE
NOTE: MEANS REPRESENT THE MEAN OF THE DAILY VALUES

REPORT 4
VERSION 1.09
2/22/2007 12:44

STUDY SPECIFICATIONS: 534006
DATE IN: 11/28/06 TIME IN: 7:00
DATE OUT: 12/13/06 TIME OUT: 16:00

ROOM SPECIFICATIONS: B ROOM 127
SPECIES: RAT
LOW TEMPERATURE °F: 66.0 HIGH TEMPERATURE °F: 76.0 LOW HUMIDITY: 30.0
LOW TEMPERATURE °C: 18.9 HIGH TEMPERATURE °C: 24.4 HIGH HUMIDITY: 70.0

	TEMPERATURE		HUMIDITY
DATE	MEAN (°F)	MEAN (°C)	MEAN (%RH)

GRAND STATS	MEAN	MIN	MAX
TEMPERATURE °F	70.5	70.2	70.6
TEMPERATURE °C	21.4	21.2	21.4
HUMIDITY (%RH)	37.6	29.3 -	45.9
N DAYS	16		

NOTE: + = VALUE WAS GREATER THAN HIGH RANGE
\- = VALUE WAS LESS THAN LOW RANGE
NOTE: MEANS REPRESENT THE MEAN OF THE DAILY VALUES

ROOM SPECIFICATIONS:	B ROOM 127		
SPECIES:	RAT		
LOW TEMPERATURE:	66.0	DATE IN:	11/28/06
HIGH TEMPERATURE:	76.0	TIME IN:	7:00
LOW HUMIDITY:	30.0	DATE OUT:	12/13/06
HIGH HUMIDITY:	70.0	TIME OUT:	16:00

ROOM B ROOM 127 SUMMARY

	TEMPERATURE	HUMIDITY
MEAN	70.5	37.5
MIN	64.7	14.8
MAX	73.9	54.2
SD	0.61	6.15
N SAMPLES	370	370
FIRST DAY	11/28/06	
LAST DAY	12/13/06	
N DAYS	16	

NOTE: TEMPERATURE UNITS = DEGREES FAHRENHEIT
HUMIDITY UNITS = % RELATIVE HUMIDITY
NOTE: MEANS REPRESENT THE MEAN OF ALL VALUES

STUDY 534006 SUMMARY

MEAN	70.5	37.5
MIN	64.7	14.8
MAX	73.9	54.2
SD	0.61	6.15
N SAMPLES	370	370
FIRST DAY	11/28/06	
LAST DAY	12/13/06	
N DAYS	16	

NOTE: TEMPERATURE UNITS = DEGREES FAHRENHEIT
HUMIDITY UNITS = % RELATIVE HUMIDITY
NOTE: MEANS REPRESENT THE MEAN OF ALL VALUES

APPENDIX E

Bioanalytical Report [_____]

534006

PHARMACOKINETIC (IN BLOOD) AND EXCRETION STUDY OF [ ] IN RATS

Analyses Of Biological Samples

[ ]

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1. INTRODUCTION

This report provides a detailed description and validation of a high performance liquid chromatography tandem mass spectrometry (HPLC/MS/MS) method in the negative electrospray ionization (ESI-) mode for the determination of [ ] concentration in rat serum. The method was validated over the concentration range of 10.0 to 1000 ng [ ]/mL of rat serum using a 50-µL sample. The method was cross-validated over the concentration range of 10.0 to 1000 ng [ ]/mL of rat urine using a 50-µL sample. Analyte stability in stock solutions and in stored rat serum and urine samples was assessed. [ ] in stock solutions was stable for at least 11 days of refrigerated storage. [ ] in rat serum was stable through at least 3 freeze-thaw cycles, for at least 4 hours of room temperature storage and for at least 124 days of frozen (approximately -20°C) storage. [ ] in rat urine was stable through at least 6 freeze-thaw cycles, for at least 4 hours of room temperature storage and for at least 127 days of frozen (approximately -20°C) storage.

This report also details the analytical results for the determination of [ ] concentration in rat serum and urine samples. Analysis of experimental serum samples resulted in levels ranging from less than the lower limit of quantitation (<LLOQ; 10.0 ng/mL) to 100,720 ng [ ]/mL. Analysis of experimental urine samples resulted in total [ ] values ranging from 4.44 to 898 µg. Analysis of experimental cage rinse samples resulted in total [ ] values ranging from 1.87 to 1006 µg. The results of the sample analyses (Tables 13 and 14) and the supporting data (Attachment I) are included in this report.

The method for the determination of [ ] in rat serum, urine and cage rinse used acetonitrile (ACN) to de-proteinize 50 µL of serum or urine. Following centrifugation, a portion of each supernatant fraction was collected, evaporated and reconstituted in mobile phase. The samples were analyzed with an HPLC/MS/MS assay using an ACE C8

column (50 × 2.1 mm). The [ ] peak areas (y) and the theoretical concentrations of calibration samples were fit to a linear regression with $1/x^2$ weighting, excluding the origin.

2. EXPERIMENTAL

2.1. IDENTIFICATION OF BLANK SERUM AND URINE

Blank rat serum and urine was purchased from Bioreclamation, East Meadow, New York. Blank serum and urine was stored frozen at approximately -20°C. Blank cage rinse was collected at [ ].

2.2. INSTRUMENTS

The mass spectrometers used were an Applied Biosystems/MDS Sciex API 4000™ or an Applied Biosystems/MDS Sciex API 5000™ tandem quadrupole mass spectrometer (hereafter referred to as API 4000 or API 5000) equipped with a TurboIonSpray™ probe for ESI+ ionization. The HPLC systems used were an Agilent 1200 liquid chromatograph (used with the API 4000) equipped with an autosampler or a Spark Holland, Inc. Symbiosis Pharma System (used with the API 5000) equipped with an autosampler. Data acquisition and analysis were performed using Analyst® software version 1.4.2. The retention time, run time and mass spectrometer settings may have varied depending on column and mass spectrometer performance.

2.2.1. HIGH PERFORMANCE LIQUID CHROMATOGRAPHY

Analytical Column:	ACE C8, 2.1 × 50 mm
Column Temperature:	Ambient 20°C on Agilent 1200
Mobile Phase:	2 mM ammonium acetate in 70:30 (v/v) deionized water:ACN
Detector:	Mass spectrometer with conditions as described in Sections 2.3. and 2.4.
Flow Rate:	0.3 mL/minute
Injection Volume:	2 to 25 µL

Retention Time:	Approximately 3.0 to 3.5 minutes for [ ] (Agilent 1200) Approximately 4.6 to 6.2 minutes for [ ] (Symbiosis)
Run Time:	Approximately 7.0 minutes (Agilent 1200) Approximately 8.0 minutes (Symbiosis)

2.3. MASS SPECTROMETRY (API 4000)

Acquisition Parameters

Scan Type:	Multiple reaction monitoring
Polarity:	Negative
Scan Mode:	Not Applicable
Ion Source:	Turbo Spray
Resolution Q1:	Unit
Resolution Q3:	Unit
Intensity Threshold:	0.00 cps
Settling Time:	0.00 msec
MR Pause:	5.0070 msec
MCA:	No
Step Size:	0.00 amu

Analyte	Q1 Mass (amu)	Q3 Mass (amu)	Dwell (msec)	Parameter	Start/Stop
[					]

DP = Declustering Potential
CE = Collision Energy
CXP = Collision Cell Exit Potential

Parameter Table

CUR (Curtain Gas):	40.00
GS1 (Gas 1):	60.00
GS2 (Gas 2):	60.00
IS (IonSpray Voltage):	-4000.00
TEM (Temperature):	450.00
ihe (Interface Heater):	OFF
CAD (Collisionally Activated Dissociation Gas):	4.00 (nitrogen)
EP (Entrance Potential):	-8.00

Detector Parameters (Positive)

CEM (Channel Electron Multiplier):	2000.0
DF (Deflector):	300.0

2.4. MASS SPECTROMETRY (API 5000)

Acquisition Parameters

Scan Type:	Multiple reaction monitoring
Polarity:	Negative
Scan Mode:	Not Applicable
Ion Source:	Turbo Spray
Resolution Q1:	Unit
Resolution Q3:	Unit
Intensity Threshold:	0.00 cps
Settling Time:	0.00 msec
MR Pause:	5.0070 msec
MCA:	No
Step Size:	0.00 amu

Analyte	Q1 Mass (amu)	Q3 Mass (amu)	Dwell (msec)	Parameter	Start/Stop
[					]

DP = Declustering Potential
CE = Collision Energy
CXP = Collision Cell Exit Potential

Parameter Table

CUR (Curtain Gas):	10.00
GS1 (Gas 1):	70.00
GS2 (Gas 2):	20.00
IS (IonSpray Voltage):	-4000.00
TEM (Temperature):	450.00
ihe (Interface Heater):	ON
CAD (Collisionally Activated Dissociation Gas):	4.00 (nitrogen)
EP (Entrance Potential):	-12.00

Detector Parameters (Positive)

CEM (Channel Electron Multiplier):	2600.0
DF (Deflector):	200.0

2.5. PREPARATION OF MOBILE PHASE

The mobile phase/diluent [2 mM ammonium acetate in 70:30 (v/v) deionized water:acetonitrile] was prepared by dissolving approximately 0.154 g of ammonium acetate in 700 mL of deionized (DI) water. ACN (300 mL) was added and the solution was stirred to achieve complete dissolution. The mobile phase was filtered through a 0.2- or 0.45-µm pore-size nylon membrane filter and vacuum-degassed. The preparation was scaled as needed.

2.6. PREPARATION OF THE [ ] CALIBRATION STOCK SOLUTION - 0.1 MG/ML

A calibration stock solution was prepared at a concentration of 0.1 mg [ ]/mL as follows. Approximately 0.010 g of [ ] was accurately weighed in a tared glass weigh funnel and transferred to a 100-mL volumetric flask with rinses of DI water. Additional DI water was added to yield the desired concentration, and the solution was stirred to achieve complete dissolution. The solution was stored at approximately 4°C.

2.7. PREPARATION OF THE [ ] CALIBRATION STOCK SOLUTION - 1.0 MG/ML

A calibration stock solution was prepared at a concentration of 1.0 mg [ ]A/mL as follows. Approximately 0.100 g of [ ] was accurately weighed in a tared glass weigh funnel and transferred to a 100-mL volumetric flask with rinses of DI water. Additional DI water was added to yield the desired concentration, and the solution was stirred to achieve complete dissolution. The solution was stored at approximately 4°C.

2.8. PREPARATION OF THE [ ] QUALITY CONTROL STOCK SOLUTION

A quality control (QC) stock solution was prepared at a concentration of 1.0 mg [ ]/mL as follows. Approximately 0.100 g of [ ] was accurately weighed in a tared glass weigh funnel and transferred to a 100-mL volumetric flask with

rinses of DI water. Additional DI water was added to yield the desired concentration, and the solution was stirred to achieve complete dissolution. The preparation was scaled as needed. The solution was stored at approximately 4°C.

2.9. PREPARATION OF CALIBRATION SAMPLES

An aliquot (100 µL) of the 1.0 mg/mL calibration stock solution was combined with 0.9 mL of DI water to prepare a 100,000 ng/mL working solution (the 0.1 mg/mL calibration stock solution was used without further dilution). Serial dilutions of the 100,000 ng/mL working or stock solution were prepared in polypropylene tubes with blank serum or urine to prepare calibration samples containing 10.0 to 1000 ng [ ]/mL. The calibration samples were processed as described in Section 2.11. (Sample Processing).

2.10. PREPARATION OF QUALITY CONTROL SAMPLES

An aliquot (20 µL) of the QC stock solution was combined with 1.98 mL of blank rat serum, urine or cage rinse to prepare a 10,000 ng/mL sample. Serial dilutions of the 10,000 ng/mL sample were prepared in polypropylene tubes with blank serum, urine or cage rinse to prepare QC samples containing 30.0 to 750 ng [ ]/mL. Dilutional QC samples were prepared by diluting aliquots of the 10,000 ng/mL QC samples up to 20-fold with blank serum, urine or cage rinse. Dilutional QC samples were also prepared by combining an aliquot of the QC stock solution with matrix to yield QC samples at either 30,000 or 150,000 ng [ ]/mL. The 30,000 and 150,000 ng/mL QC samples were diluted up to 1000- or 5000-fold, respectively, with blank matrix. The QC samples were processed as described in Section 2.11. (Sample Processing).

2.11. SAMPLE PROCESSING

Aliquots (50 µL) of the calibration, QC and experimental samples were transferred to 1.5-mL conical tubes. Dilutional QC samples were diluted up to 5000-fold with blank serum or urine and 50-µL aliquots were transferred to 1.5-mL conical tubes. Experimental samples were diluted up to 5000-fold with blank serum or urine when the

initial assayed or expected concentrations were greater than 1000 ng [ ]/mL, and 50-µL aliquots were transferred to 1.5-mL conical tubes. ACN (0.15 mL) was added to the 1.5-mL conical tubes containing the calibration, QC and experimental samples. The tubes were capped, and the samples were thoroughly mixed for a minimum of 2 minutes. The samples were centrifuged at 10,000 rpm for approximately 5 minutes. An aliquot (150 µL) of each supernatant fraction was transferred to a 96-well plate. Samples were evaporated to dryness under a stream of nitrogen and reconstituted in 150 µL of mobile phase.

2.12. CONCENTRATION QUANTITATION

A calibration curve was constructed using Analyst®. The [ ] peak areas (y) and the theoretical concentrations of the calibration standards (x) were fit to a quadratic function with a $1/x^2$ weighting, excluding the origin. Concentration and percent relative error (%RE) were calculated using Analyst®.

3. RESULTS AND DISCUSSION

3.1. METHOD VALIDATION

The method for the determination of [ ] concentration in rat serum, urine and cage rinse was validated, and method sensitivity, specificity/selectivity, calibration reproducibility, ruggedness, accuracy and precision were assessed. The results of the validation are summarized in Tables 1 and 2 (Calibration Samples) and Tables 3 through 5 (QC Samples).

Under the described chromatographic conditions, the retention time for [ ] was approximately 3.0 to 3.5 minutes (Agilent 1200) or approximately 4.6 to 6.2 minutes (Symbiosis). The total run time for each analysis was approximately 7.0 minutes (Agilent 1200) or approximately 8.0 minutes (Symbiosis). Figures 1 through 35 illustrate typical chromatograms of blank samples (Figures 1 and 2), processed rat serum calibration samples (Figures 3 through 9), processed rat serum QC samples (Figures 10 through 13) and processed serum experimental samples (Figures 14 through 35).

Figures 36 through 57 illustrate typical chromatograms of blank samples (Figure 36), processed rat urine calibration samples (Figures 37 through 43), processed rat urine and cage rinse QC samples (Figures 44 through 51) and processed urine and cage rinse experimental samples (Figures 52 through 57).

3.2. SENSITIVITY

The lower limit of quantitation (LLOQ) can be defined as the lowest calibration concentration that meets the validation acceptance criteria [i.e., relative standard deviation (RSD) ≤ 20% and percent relative error (%RE) within ± 20%]. As shown in Tables 1 and 2, the LLOQ was 10.0 ng/mL for [ ] in rat serum and urine. The inter-session (serum) and intra-session (urine) RSD and %RE values at the LLOQ are detailed in the following table.

	%RSD	%RE
Rat serum	4.4	0.82
Rat urine	6.5	1.2

3.3. SPECIFICITY/SELECTIVITY

Assay specificity/selectivity refers to the ability of the assay to specifically detect and quantitate the analyte(s) of interest from potentially interfering compounds. Assay specificity/selectivity was confirmed when assessment of the assay accuracy and precision met the acceptance criteria.

3.4. RUGGEDNESS

Assay ruggedness was successfully demonstrated for this procedure because more than 1 analyst successfully performed at least 1 of the validation sessions.

3.5. CALIBRATION ACCEPTABILITY

During each validation session, triplicate calibration samples at 5 concentrations were prepared and analyzed. The resulting analyte peak area versus theoretical concentration data were fit to the quadratic function with $1/x^2$ weighting, excluding the origin, using

least-squares regression analysis. The results of the regression analyses were used to back-calculate the corresponding concentrations from the peak area data. The reproducibility of the calibration curve data was considered valid when 1) the inter- or intra-session variability, expressed as %RSD, of the back-calculated concentrations at each calibration level was ≤ 15%, except at the lowest calibration level where ≤ 20% was acceptable; and 2) the mean back-calculated concentrations at each calibration level were within 15% of the theoretical values (%RE within ± 15%), except at the lowest calibration level where %RE within ± 20% was acceptable.

The back-calculated concentrations and the associated intra- and inter-session statistics for [ ] calibration samples used during the validation in rat serum and urine are shown in Tables 1 and 2. The inter-session variability of the back-calculated concentrations at each rat serum calibration level ranged from 1.2% to 4.4% RSD. The inter-session mean concentrations had %RE values ranging from -2.7% to 2.1%. The intra-session variability of the back-calculated concentrations at each rat urine calibration level ranged from 5.8% to 13% RSD. The intra-session mean concentrations had %RE values ranging from -3.3% to 4.4%. Based on the stated criteria, the reproducibility of the calibration data was acceptable.

3.6. ACCURACY AND PRECISION

During each validation session, triplicate QC samples at a minimum of 3 concentrations were prepared and analyzed as described previously. Single injections were made of each processed QC sample. The results of the regression analyses were used to calculate the corresponding concentrations from the QC peak area data. The variability (RSD) of calculated QC concentration data was used as a measure of assay precision. The precision of the method was considered acceptable when the inter- or intra-session RSD of the calculated concentrations at each QC level was ≤ 15%. The difference between the theoretical and mean calculated QC concentrations (%RE) was used as a measure of assay accuracy. The accuracy of the method was considered acceptable when

the inter- or intra-session mean calculated concentration at each QC level had a %RE value within ± 15%.

The calculated concentrations and the associated intra- and inter-session statistics for the [ ] assay QC samples used during the validation in rat serum, urine and cage rinse are summarized in Tables 3 through 5. The inter-session variability and the %RE values for the inter- (serum) or intra- (urine and cage rinse) session mean concentrations are summarized in the following table.

	%RSD	%RE
Rat serum	4.4 to 6.3	-4.9 to 3.6
Rat urine	6.5 to 14	-6.7 to 11
Rat cage rinse	1.8 to 4.3	-6.7 to 3.3

Based on the stated criteria, the precision and accuracy of the [ ] assays were acceptable.

3.7. STABILITY

Stability of [ ] was evaluated in stock solutions and in samples after short-term (4 hours) room temperature storage, during the freeze-thaw process and during frozen storage. According to the protocol, stability was verified if the mean measured post-storage (or treatment) analyte concentration was not less than 85% of the corresponding time-zero concentration.

3.7.1. STABILITY OF [ ] IN REFRIGERATED STOCK SOLUTIONS

Stability of [ ] in stock solutions was evaluated. Standards at 400 ng/mL in water were prepared from stock solutions after 11 days of refrigerated storage. The [ ] peak areas of the standards prepared after storage of the stock solution were compared to standards prepared from the freshly prepared (day 0) standard [ ] peak areas.

The mean areas of the standards prepared from stock solutions after 11 days of refrigerated storage were 99.1% of the mean time-zero area (Table 6). Therefore, [ ] in stock solutions was considered to be stable for at least 11 days of refrigerated storage.

3.7.2. LONG TERM FROZEN STABILITY OF [ ] IN SERUM AND URINE SAMPLES

Rat serum and urine samples were fortified at 30.0 and 750 ng [ ]/mL, analyzed in at least duplicate for time-zero concentration, stored frozen at approximately -20°C for up to 127 days and reanalyzed in triplicate to evaluate test article stability.

The mean measured concentrations in the rat serum samples after frozen storage of up to 124 days ranged from 94.3% to 115% of the corresponding time-zero concentrations (Table 7), which met the specified criteria. The mean measured concentrations in the rat urine samples after frozen storage of up to 127 days ranged from 107% to 113% of the corresponding time-zero concentrations (Table 8), which met the specified criteria. Therefore, [ ] in rat serum and urine samples was considered to be stable for up to 124 and 127 days of frozen (-70°C) storage, respectively.

3.7.3. STABILITY OF [ ] IN SERUM AND URINE SAMPLES AT ROOM TEMPERATURE

Blank rat serum and urine were fortified at 30.0 and 750 ng [ ]/mL, analyzed in triplicate to establish time-zero concentration, stored frozen at approximately -20°C and allowed to thaw at room temperature. After approximately 4 hours of room temperature storage, the samples were reanalyzed in triplicate to assess test article stability.

The mean measured concentrations in the 30.0 and 750 ng/mL serum samples after approximately 4 hours of room temperature storage were 110% and 94.7% of the corresponding time-zero concentrations (Table 9), which met the specified criteria for stability. The mean measured concentrations in the 30.0 and 750 ng/mL urine samples after approximately 4 hours of room temperature storage were 108% and 106% of the corresponding time-zero concentrations (Table 10), which met the specified criteria for

stability. Therefore, [ ] in rat serum and urine samples was considered to be stable for at least 4 hours of room temperature storage.

3.7.4. FREEZE-THAW STABILITY OF [ ] IN SERUM AND URINE SAMPLES

Rat serum and urine samples were fortified at 30.0 and 750 ng [ ]/mL. Triplicate samples from each concentration level were used to evaluate the stability of the analyte after each of a minimum of 3 freeze-thaw cycles. The samples were frozen at approximately -20°C and thawed (1 cycle), and the process repeated a minimum of 2 more times (cycles 2 and 3) for the analysis of freeze-thaw stability.

The mean measured concentrations in rat serum samples after up to 3 freeze-thaw cycles ranged from 96.3% to 120% of the corresponding time-zero concentrations (Table 11), which met the specified acceptance criteria. The mean measured concentrations in rat urine samples after up to 6 freeze-thaw cycles ranged from 109% to 113% of the corresponding time-zero concentrations (Table 12), which met the specified acceptance criteria. Therefore, [ ] in rat serum and urine samples was considered to be stable through at least 3 and 6 freeze-thaw cycles, respectively.

3.8. ANALYSIS OF EXPERIMENTAL SAMPLES

Rat serum and urine samples from study day 0 were analyzed for [ ] concentration. The results are summarized in Tables 13 and 14.

In addition to the experimental samples, each set of analyses consisted of at least duplicate calibration samples at 5 concentrations, 1 solvent blank, 3 blank matrix samples and at least triplicate QC samples at a minimum of 3 concentrations. Dilutional QC samples were analyzed as needed. For an analytical run to be considered valid, at least two-thirds of the QC samples (with at least 1 at each concentration level) could not deviate more than ± 15% from the QC target concentrations. Tables 15 and 16 summarize the results of the calibration and QC samples. All reported results are from analyses that met the acceptance criteria.

4. CONCLUSION

In this study, the method for the analysis of [ ] concentration in rat serum, urine and cage rinse was validated over the concentration range of 10.0 to 1000 ng [ ]/mL of matrix using a 50-µL sample. Analyte stability in stock solutions and in stored rat serum and urine samples was assessed. [ ] in stock solutions was stable for at least 11 days of refrigerated storage. [ ] in rat serum was stable through at least 3 freeze-thaw cycles, for at least 4 hours of room temperature storage and for at least 124 days of frozen (approximately -20°C) storage. [ ] in rat urine was stable through at least 6 freeze-thaw cycles, for at least 4 hours of room temperature storage and for at least 127 days of frozen (approximately -20°C) storage. Analysis of experimental serum samples resulted in levels ranging from <LLOQ to 100,720 ng [ ]/mL. Analysis of experimental urine samples resulted in total [ ] values ranging from 4.44 to 898 µg. Analysis of experimental cage rinse samples resulted in total [ ] values ranging from 1.87 to 1006 µg.

TABLES 1 - 16

PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 1: [ ] Back-Calculated Concentrations And Intra- And Inter-Session Statistics Of Calibration Samples In Rat Serum

Theo. Conc. (ng/mL)	10.0	30.0	100	300	1000
Session 1 (28 Feb 2007), I8-534006a, analyst DKP					
Sample 1	10.4	28.5	104	301	1015
Sample 2	10.4	28.8	105	296	990
Sample 3	9.41	29.0	105	286	1003
Intra-session Statistics					
n	3	3	3	3	3
Mean	10.1	28.8	105	294	1003
SD	0.60	0.26	0.77	7.7	13
RSD	5.9	0.90	0.73	2.6	1.3
%RE	0.93	-4.0	4.8	-1.9	0.26
Session 2 (28 Feb 2007), I8-534006b, analyst DKP					
Sample 1	9.95	**	97.9	318	974
Sample 2	10.3	29.9	98.3	305	982
Sample 3	9.76	30.0	98.6	299	1020
Intra-session Statistics					
n	3	2	3	3	3
Mean	10.0	29.9	98.3	307	992
SD	0.29	0.10	0.36	9.6	24
RSD	2.9	0.32	0.37	3.1	2.4
%RE	0.14	-0.17	-1.7	2.4	-0.79

** Data point not included in calculation of statistics based on test for outliers.

534006.xls Cal (serum)
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PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 1: [ ] Back-Calculated Concentrations And Intra- And Inter-Session Statistics Of Calibration Samples In Rat Serum

Theo. Conc. (ng/mL)	**10.0**	**30.0**	**100**	**300**	**1000**
Session 3 (13 Mar 2007), I8-534006g, analyst SMH					
Sample 1	10.1	27.3	103	322	1007
Sample 2	10.1	29.6	99.1	308	1000
Sample 3	10.4	26.7	104	293	981
Intra-session Statistics					
n	3	3	3	3	3
Mean	10.2	27.9	102	308	996
SD	0.16	1.5	2.5	14	14
RSD	1.6	5.5	2.5	4.6	1.4
%RE	2.1	-7.1	1.9	2.6	-0.42
Session 4 (13 Mar 2007), I8-534006h, analyst SMH					
Sample 1	10.2	29.6	98.9	302	1001
Sample 2	10.2	30.5	98.2	303	995
Sample 3	9.68	28.9	99.8	309	997
Intra-session Statistics					
n	3	3	3	3	3
Mean	10.0	29.7	99.0	305	998
SD	0.31	0.81	0.78	3.8	3.2
RSD	3.1	2.7	0.79	1.2	0.32
%RE	0.42	-1.1	-1.0	1.6	-0.22

534006.xls Cal (serum)
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PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 1: [ ] Back-Calculated Concentrations And Intra- And Inter-Session Statistics Of Calibration Samples In Rat Serum

Theo. Conc. (ng/mL)	10.0	30.0	100	300	1000
Session 5 (13 Mar 2007), I8-534006i, analyst HLC					
Sample 1	10.0	28.8	94.0	320	1003
Sample 2	10.8	29.1	93.8	322	979
Sample 3	9.29	32.4	98.1	295	1003
Intra-session Statistics					
n	3	3	3	3	3
Mean	10.0	30.1	95.3	312	995
SD	0.73	2.0	2.4	15	14
RSD	7.3	6.6	2.5	4.8	1.4
%RE	0.24	0.28	-4.7	4.1	-0.51
Session 6 (14 Mar 2007), I8-534006j, analyst HLC					
Sample 1	9.96	29.7	98.7	311	1002
Sample 2	9.44	28.4	98.8	320	998
Sample 3	10.9	29.2	97.3	302	984
Intra-session Statistics					
n	3	3	3	3	3
Mean	10.1	29.1	98.3	311	995
SD	0.75	0.67	0.83	9.2	10
RSD	7.5	2.3	0.85	2.9	0.96
%RE	1.0	-3.0	-1.7	3.6	-0.52
Inter-session Statistics					
n	18	17	18	18	18
Mean	10.1	29.2	99.6	306	996
SD	0.45	1.2	3.4	11	12
RSD	4.4	4.3	3.4	3.5	1.2
%RE	0.82	-2.7	-0.42	2.1	-0.37

534006.xls Cal (serum)
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PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 2: [ ] Back-Calculated Concentrations And Intra-Session Statistics Of Calibration Samples In Rat Urine

Theo. Conc. (ng/mL)	**10.0**	**30.0**	**100**	**300**	**1000**
Session 1 (15 Mar 2007), I8-534006l, analyst HLC					
Sample 1	9.36	29.2	110	328	1035
Sample 2	10.6	32.8	84.0	283	1017
Sample 3	10.4	25.1	99.0	328	927
Intra-session Statistics					
n	3	3	3	3	3
Mean	10.1	29.0	97.5	313	993
SD	0.66	3.9	13	26	58
RSD	6.5	13	13	8.3	5.8
%RE	1.2	-3.3	-2.5	4.4	-0.71

534006.xls Cal (urine)
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PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 3: [ ] Concentrations And Intra- And Inter-Session Statistics Of Quality Control Samples In Rat Serum

Theo. Conc. (ng/mL)	**30.0**	**250**	**750**	**10000**
Session 1 (28 Feb 2007), I8-534006a, analyst DKP				
Sample 1	28.1	238	714	9425
Sample 2	28.7	241	723	9384
Sample 3	29.2	244	723	9490
Intra-session Statistics				
n	3	3	3	3
Mean	28.6	241	720	9433
SD	0.54	3.2	5.4	54
RSD	1.9	1.3	0.75	0.57
%RE	-4.5	-3.6	-4.0	-5.7
Session 2 (28 Feb 2007), I8-534006b, analyst DKP				
Sample 1	31.3	239	748	9709
Sample 2	29.2	241	754	9685
Sample 3	28.1	248	747	9626
Intra-session Statistics				
n	3	3	3	3
Mean	29.5	243	750	9673
SD	1.6	4.6	3.8	43
RSD	5.4	1.9	0.51	0.44
%RE	-1.6	-3.0	-0.059	-3.3

534006.xls QC (serum)
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PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 3: [ ] Concentrations And Intra- And Inter-Session Statistics Of Quality Control Samples In Rat Serum

Theo. Conc. (ng/mL)	30.0	250	750	10000
Session 3 (13 Mar 2007), I8-534006g, analyst SMH				
Sample 1	30.3	268	798	***
Sample 2	26.2	268	773	***
Sample 3	32.1	274	786	***
Intra-session Statistics				
n	3	3	3	na
Mean	29.6	270	786	na
SD	3.0	3.3	12	na
RSD	10.3	1.2	1.6	na
%RE	-1.5	8.0	4.8	na
Session 4 (13 Mar 2007), I8-534006h, analyst SMH				
Sample 1	26.7	256	805	11265
Sample 2	27.5	260	815	10601
Sample 3	30.3	265	799	10886
Intra-session Statistics				
n	3	3	3	3
Mean	28.2	260	806	10917
SD	1.9	4.4	7.9	333
RSD	6.8	1.7	0.99	3.1
%RE	-6.2	4.1	7.5	9.2

na = not applicable
*** QC sample data not included due to preparation error.

534006.xls QC (serum)
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PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 3: [ ] Concentrations And Intra- And Inter-Session Statistics Of Quality Control Samples In Rat Serum

Theo. Conc. (ng/mL)	**30.0**	**250**	**750**	**10000**
Session 5 (13 Mar 2007), I8-534006i, analyst HLC				
Sample 1	27.7	245	788	10142
Sample 2	25.2	247	807	10242
Sample 3	28.9	271	826	10656
Intra-session Statistics				
n	3	3	3	3
Mean	27.2	254	807	10347
SD	1.9	15	19	273
RSD	7.0	5.8	2.4	2.6
%RE	-9.2	1.8	7.5	3.5
Session 6 (14 Mar 2007), 534006j, analyst HLC				
Sample 1	28.7	246	807	***
Sample 2	28.5	246	772	***
Sample 3	26.8	249	802	***
Intra-session Statistics				
n	3	3	3	na
Mean	28.0	247	794	na
SD	1.1	1.7	19	na
RSD	3.8	0.69	2.4	na
%RE	-6.7	-1.2	5.8	na
Inter-session Statistics				
n	18	18	18	12
Mean	28.5	253	777	10093
SD	1.8	12	34	636
RSD	6.2	4.8	4.4	6.3
%RE	-4.9	1.0	3.6	0.93

*** QC sample data not included due to preparation error.
na = not applicable

534006.xls QC (serum)
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Table 4: [ ] Concentrations And Intra-Session Statistics Of Quality Control Samples In Rat Urine

Theo. Conc. (ng/mL)	30.0	250	750	10000
Session 1 (15 Mar 2007), I8-534006l, analyst HLC				
Sample 1	27.9	242	793	9978
Sample 2	36.6	216	903	12540
Sample 3	34.7	242	801	10064
Intra-session Statistics				
n	3	3	3	3
Mean	33.1	233	832	10861
SD	4.6	15	62	1455
RSD	14	6.5	7.4	13
%RE	10	-6.7	11	8.6

534006.xls QC (urine)
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PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 5: [ ] Concentrations And Intra-Session Statistics Of Quality Control Samples In Cage Rinse

Theo. Conc. (ng/mL)	**30.0**	**250**	**750**	**30000**
Session 1 (28 Mar 2007), I6-534006l1, analyst SMH				
Sample 1	31.2	240	750	27523
Sample 2	29.4	232	783	28519
Sample 3	29.9	253	783	27956
Intra-session Statistics				
n	3	3	3	3
Mean	30.2	242	772	27999
SD	0.91	11	19	499
RSD	3.0	4.3	2.4	1.8
%RE	0.56	-3.3	3.0	-6.7

534006.xls QC (cage rinse)
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PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 6: Refrigerated (4°C) Stability Of [ ] In DI Water Stock Solutions

Storage Duration (days)	Run # (534006-)	Ref. # (534006-)	Area	Mean Area	RSD (%)	% of Time Zero
0[a]	I6-1109	201-6	26400000	26500000	0.53	NA
	I6-1110	201-8	26600000			
11[a]	I6-1107	201-2	26400000	26250000	0.81	**99.1**
	I6-1108	201-4	26100000			

a. Results for Time Zero and 11-day were in Sequence I6-534006j

NA = not applicable

534006.xls Stock
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PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 7: Stability of [ ] In Rat Serum - Long-Term Frozen (-20°C) Storage

Theo. Conc. (ng/mL)	Storage Duration (Days)	Run# (534006-)	Ref. # (534006-)	Assay Conc. (ng/mL)	Mean Conc. (ng/mL)	SD	RSD (%)	% of Theo.	% of Time Zero
30.0	0[a]	I6-0684	155-2	28.0	27.7	0.46	1.7	92.3	na
	0[a]	I6-0723	155-3	27.4					
	11[b]	I6-1155	209-1	30.5	30.8	0.58	1.9	103	111
	11[b]	I6-1156	209-2	31.5					
	11[b]	I6-1157	209-3	30.5					
	124[c]	I6-1675	264-1	31.0	31.9	0.86	2.7	106	115
	124[c]	I6-1676	264-2	32.2					
	124[c]	I6-1677	264-3	32.6					
750	0	I6-0686	155-8	823	806	24	2.9	107	na
	0	I6-0725	155-9	789					
	11	I6-1158	209-4	773	765	6.7	0.87	102	95.0
	11	I6-1159	209-5	760					
	11	I6-1160	209-6	764					
	124	I6-1678	264-4	772	760	11	1.5	101	94.3
	124	I6-1679	264-5	750					
	124	I6-1680	264-6	759					

a. Results for 0 day were in Sequence I6-534006f1
b. Results for 11 days were in Sequence I6-534006k
c. Results for 124 days were in Sequence I6-534006p1

na= not applicable

534006.xls LT (serum)
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PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 8: Stability of [ ] In Rat Urine - Long-Term Frozen (-20°C) Storage

Theo. Conc. (ng/mL)	Storage Duration (Days)		Run# (534006-)	Ref. # (534006-)	Assay Conc. (ng/mL)	Mean Conc. (ng/mL)	SD	RSD (%)	% of Theo.	% of Time Zero
30.0	0	a	I6- 0751	165-1	27.4	27.1	1.3	4.8	90.5	na
	0	a	I6-0 780	165-2	25.8					
	0	a	I6-0 804	165-3	28.3					
	14	b	I6-1411	235-1	31.6	30.3	1.2	3.8	101	112
	14	b	I6-1412	235-2	30.0					
	14	b	I6-1413	235-3	29.3					
	127	c	I6-1800	273-1	31.4	28.9	2.9	10	96.5	107
	127	c	I6-1801	273-2	25.7					
	127	c	I6-1802	273-3	29.8					
750	0	a	I6-0753	165-7	697	743	41	5.5	99.0	na
	0	a	I6-0782	165-8	775					
	0	a	I6-0806	165-9	755					
	14	b	I6-1420	235-10	809	839	36	4.2	112	113
	14	b	I6-1421	235-11	878					
	14	b	I6-1422	235-12	831					
	127	c	I6-1803	273-4	782	836	50	6.0	111	113
	127	c	I6-1804	273-5	845					
	127	c	I6-1805	273-6	881					

a. Results for 0 day were in Sequence I6-534006g
b. Results for 14 days were in Sequence I6-534006m
c. Results for 127 days were in Sequence I6-534006q1

na= not applicable

534006.xls LT (urine)
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PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 9: Room Temperature Stability Of [ ] In Rat Serum

Theo. Conc. (ng/mL)	Storage Duration (hours)	Run # (534006-)	Ref. # (534006-)	Analyzed Conc (ng/mL)	% Target	Mean Conc (ng/mL)	RSD (%)	Mean % Target	% of Time Zero
30.0	0[a]	I6-0684	155-2	28.0	93.4	27.7	1.7	92.3	NA
		I6-0723	155-3	27.4	91.2				
	4[b]	I6-1175	210-1	30.2	101	30.4	0.56	101	**110**
	(approximately)	I6-1176	210-2	30.4	101				
		I6-1177	210-3	30.6	102				
750	0[a]	I6-0686	155-8	823	110	806	2.9	107	NA
		I6-0725	155-9	789	105				
	4[b]	I6-1178	210-4	763	102	763	1.1	102	**94.7**
	(approximately)	I6-1179	210-5	772	103				
		I6-1180	210-6	755	101				

a. Results for Time Zero were in Sequence I6-534006f1
b. Results for 4-hour were in Sequence I6-534006k

NA = not applicable

534006.xls ST (serum)
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PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 10: Room Temperature Stability Of [ ] In Rat Urine

Theo. Conc. (ng/mL)	Storage Duration (hours)	Run # (534006-)	Ref. # (534006-)	Analyzed Conc (ng/mL)	% Target	Mean Conc (ng/mL)	RSD (%)	Mean % Target	% of Time Zero
30.0	0[a]	I6- 0751	165-1	27.4	91.3	27.1	4.8	90.5	NA
		I6-0780	165-2	25.8	85.8				
		I6-0804	165-3	28.3	94.3				
	4[b]	I6-1391	233-1	31.2	104	29.4	5.5	98.0	**108**
	(approximately)	I6-1392	233-2	28.6	95.4				
		I6-1393	233-3	28.3	94.3				
750	0[a]	I6-0753	165-7	697	92.9	743	5.5	99.0	NA
		I6-0780	165-8	775	103				
		I6-0806	165-9	755	101				
	4[b]	I6-1394	233-4	761	102	785	4.6	105	**106**
	(approximately)	I6-1395	233-5	766	102				
		I6-1396	233-6	826	110				

a. Results for Time Zero were in Sequence I6-534006g
b. Results for 4-hour were in Sequence I6-534006m

NA = not applicable

534006.xls ST (urine)
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PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 11: Freeze-Thaw Stability Of [ ] In Rat Serum

Theo. Conc. (ng/mL)	# of Cycles	Run # (534006-)	Ref. # (534006-)	Analyzed Conc (ng/mL)	% Target	Mean Conc (ng/mL)	RSD (%)	Mean % Target	% of Time Zero
30.0	0[a]	I6-0684	155-2	28.0	93.4	27.7	1.7	92.3	NA
		I6-0723	155-3	27.4	91.2				
	1[b]	I6-1694	265-1	31.9	106	32.2	1.2	107	**116**
		I6-1695	265-2	32.1	107				
		I6-1696	265-3	32.6	109				
	2	I6-1697	265-4	32.7	109	33.0	1.0	110	**119**
		I6-1698	265-5	33.4	111				
		I6-1699	265-6	32.9	110				
	3	I6-1700	265-7	33.9	113	33.2	2.1	111	**120**
		I6-1701	265-8	33.0	110				
		I6-1702	265-9	32.6	109				
750	0[a]	I6-0686	155-8	823	110	806	2.9	107	NA
		I6-0725	155-9	789	105				
	1[b]	I6-1703	265-10	784	105	778	0.92	104	**96.6**
		I6-1704	265-11	780	104				
		I6-1705	265-12	770	103				
	2	I6-1706	265-13	768	102	776	2.2	103	**96.3**
		I6-1707	265-14	765	102				
		I6-1708	265-15	795	106				
	3	I6-1709	265-16	790	105	792	0.26	106	**98.2**
		I6-1710	265-17	792	106				
		I6-1711	265-18	794	106				

a. Results for Time Zero were in Sequence I6-534006f1
b. Results for cycles 1 through 3 were in Sequence I6-534006p1

534006.xls F-T (serum)
NA = not applicable
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PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 12: Freeze-Thaw Stability Of [ ] In Rat Urine

Theo. Conc. (ng/mL)	# of Cycles	Run # (534006-)	Ref. # (534006-)	Analyzed Conc (ng/mL)	% Target	Mean Conc (ng/mL)	RSD (%)	Mean % Target	% of Time Zero
30.0	0[a]	I6- 0751	165-1	27.4	91.3	27.1	4.8	90.5	NA
		I6-0780	165-2	25.8	85.8				
		I6-0804	165-3	28.3	94.3				
	1[b]	I6-1411	235-1	31.6	105	30.3	3.8	101	**112**
		I6-1412	235-2	30.0	100				
		I6-1413	235-3	29.3	97.6				
	2	I6-1414	235-4	31.2	104	29.8	5.3	99.2	**110**
		I6-1415	235-5	28.1	93.6				
		I6-1416	235-6	30.0	99.9				
	3	I6-1417	235-7	30.7	102	29.5	3.7	98.4	**109**
		I6-1418	235-8	28.5	95.0				
		I6-1419	235-9	29.4	98.0				
	6[c]	I6-1819	274-1	32.9	110	30.8	6.2	103	**113**
		I6-1820	274-2	29.9	99.6				
		I6-1821	274-3	29.5	98.2				

NA = not applicable

a. Results for cycle 0 were in Sequence I6-534006g
b. Results for cycles 1 to 3 were in Sequence I6-534006m
c. Results for cycle 6 were in Sequence I6-534006q1

PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 12: Freeze-Thaw Stability Of [ ] In Rat Urine (Continued)

Theo. Conc. (ng/mL)	# of Cycles	Run # (534006-)	Ref. # (534006-)	Analyzed Conc (ng/mL)	% Target	Mean Conc (ng/mL)	RSD (%)	Mean % Target	% of Time Zero
750	0[a]	I6-0753	165-7	697	92.9	743	5.5	99.0	NA
		I6-0782	165-8	775	103				
		I6-0806	165-9	755	101				
	1[b]	I6-1420	235-10	809	108	839	4.2	112	**113**
		I6-1421	235-11	878	117				
		I6-1422	235-12	831	111				
	2	I6-1423	235-13	861	115	810	15	108	**109**
		I6-1424	235-14	899	120				
		I6-1425	235-15	668	89.1				
	3	I6-1426	235-16	823	110	817	6.8	109	**110**
		I6-1427	235-17	759	101				
		I6-1428	235-18	870	116				
	6[c]	I6-1822	274-4	830	111	825	6.5	110	**111**
		I6-1823	274-5	770	103				
		I6-1824	274-6	876	117				

NA = not applicable

a. Results for cycle 0 were in Sequence I6-534006g
b. Results for cycles 1 to 3 were in Sequence I6-534006m
c. Results for cycle 6 were in Sequence I6-534006q1

534006.xls F-T (urine)
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PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 13: Rat Serum Experimental Sample [ ] Concentration Data

Ref. # (534006-)	Animal No.	Day	Group	Sex	Timepoint (hrs)	[ ] Conc. (ng/mL)	
195-1	46662	0	1	M	0	< LLOQ	1
195-2	46663	0	1	M	0	< LLOQ	
195-3	46665	0	1	M	0	< LLOQ	
195-4	46678	0	1	F	0	< LLOQ	
195-5	46679	0	1	F	0	< LLOQ	
195-6	46680	0	1	F	0	< LLOQ	
196-1	46666	0	1	M	0.0333	85509	
196-2	46669	0	1	M	0.0333	16736	
196-3	46672	0	1	M	0.0333	100720	
196-4	46681	0	1	F	0.0333	88738	
196-5	46684	0	1	F	0.0333	98125	
196-6	46685	0	1	F	0.0333	97362	
196-7	46673	0	1	M	0.167	71736	
196-8	46674	0	1	M	0.167	59438	
196-9	46676	0	1	M	0.167	76212	
196-10	46686	0	1	F	0.167	53064	
196-11	46688	0	1	F	0.167	43359	
196-12	46691	0	1	F	0.167	54242	
196-13	46662	0	1	M	0.333	65371	
196-14	46663	0	1	M	0.333	55817	
196-15	46665	0	1	M	0.333	65870	
196-16	46678	0	1	F	0.333	30804	
196-17	46679	0	1	F	0.333	27712	
196-18	46680	0	1	F	0.333	31506	
197-1	46666	0	1	M	0.5	51702	
197-2	46669	0	1	M	0.5	19975	
197-3	46672	0	1	M	0.5	57560	
197-4	46681	0	1	F	0.5	27329	
197-5	46684	0	1	F	0.5	24091	
197-6	46685	0	1	F	0.5	19724	

1. < LLOQ = not detected or less than the lower limit of quantitation (10 ng/mL)

534006.xls Summary (serum)
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PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 13: Rat Serum Experimental Sample [ ] Concentration Data

Ref. # (534006-)	Animal No.	Day	Group	Sex	Timepoint (hrs)	[ ] Conc. (ng/mL)	
197-7	46673	0	1	M	1	62374	
197-8	46674	0	1	M	1	47426	
197-9	46676	0	1	M	1	81376	
197-10	46686	0	1	F	1	15651	
208-1	46688	0	1	F	1	10027	
197-12	46691	0	1	F	1	17595	
198-1	46662	0	1	M	3	37375	
198-2	46663	0	1	M	3	15238	
198-3	46665	0	1	M	3	22245	
198-4	46678	0	1	F	3	1028	
158-17	46679	0	1	F	3	992	
158-18	46680	0	1	F	3	625	
198-5	46666	0	1	M	5	8627	
198-6	46669	0	1	M	5	20677	
198-7	46672	0	1	M	5	17947	
158-22	46681	0	1	F	5	639	
158-23	46684	0	1	F	5	285	
158-24	46685	0	1	F	5	160	
198-8	46673	0	1	M	7	24227	
198-9	46674	0	1	M	7	7111	
198-10	46676	0	1	M	7	20778	
159-4	46686	0	1	F	7	409	
159-5	46688	0	1	F	7	77.0	
159-6	46691	0	1	F	7	176	
159-7	46662	0	1	M	24	395	
159-8	46663	0	1	M	24	73.2	
159-9	46665	0	1	M	24	106	
159-10	46678	0	1	F	24	13.2	
159-11	46679	0	1	F	24	9.90	
159-12	46680	0	1	F	24	12.5	
159-13	46666	0	1	M	48	18.3	
159-14	46669	0	1	M	48	178	
159-15	46672	0	1	M	48	23.0	
159-16	46681	0	1	F	48	13.4	
159-17	46684	0	1	F	48	< LLOQ	1
159-18	46685	0	1	F	48	13.5	

1. < LLOQ = not detected or less than the lower limit of quantitation (10 ng/mL)

534006.xls Summary (serum)
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PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 14: Rat Urine/Cage Rinse Experimental Sample [ ] Concentration Data

Ref. # (534006-)	Animal No.	Timepoint	Matrix	[ ] Conc. (ng/mL)	Urine/ Cage Rinse Volume (mL)	Total [ ] (µg)
221-1	46664	0-6 hr	urine	345340	2.6	898
221-4	46670	0-6 hr	urine	394510	1.4	552
221-5	46682	0-6 hr	urine	564250	1.3	734
230-1	46683	0-6 hr	urine	1533800	0.3	460
221-8	46690	0-6 hr	urine	394380	2.0	789
231-1	46664	0-6 hr	cage rinse	10363	11	114
221-3	46667	0-6 hr	cage rinse	96774	10.4	1006
222-1	46670	0-6 hr	cage rinse	4828	13.2	63.7
222-2	46682	0-6 hr	cage rinse	8214	10.6	87.1
221-7	46683	0-6 hr	cage rinse	12178	13.4	163
222-3	46690	0-6 hr	cage rinse	7205	11.8	85.0
221-9	46664	6-12 hr	urine	141640	4.4	623
221-10	46667	6-12 hr	urine	104600	4.6	481
221-11	46670	6-12 hr	urine	89395	5.6	501
253-1	46682	6-12 hr	urine	12069	4.4	53.1
221-13	46683	6-12 hr	urine	74686	4.2	314
221-14	46690	6-12 hr	urine	113540	4.0	454
222-4	46664	6-12 hr	cage rinse	3614	14.0	50.6
222-5	46667	6-12 hr	cage rinse	1849	14.0	25.9
222-6	46670	6-12 hr	cage rinse	2295	14.0	32.1
167-19	46682	6-12 hr	cage rinse	671	14.8	9.94
222-7	46683	6-12 hr	cage rinse	2118	17.0	36.0
222-8	46690	6-12 hr	cage rinse	2038	15.8	32.2
221-15	46664	12-24 hr	urine	8082	12.6	102
221-16	46667	12-24 hr	urine	15157	9.0	136
221-17	46670	12-24 hr	urine	8782	10.8	94.8
254-1	46682	12-24 hr	urine	1200	7.2	8.64
232-2	46683	12-24 hr	urine	1315	6.2	8.16
168-11	46690	12-24 hr	urine	616	7.2	4.44
168-2	46664	12-24 hr	cage rinse	753	14.0	10.5
222-9	46667	12-24 hr	cage rinse	948	7.8	7.40
168-6	46670	12-24 hr	cage rinse	632	9.8	6.20
168-8	46682	12-24 hr	cage rinse	238	10.9	2.59
168-10	46683	12-24 hr	cage rinse	342	10.8	3.70
168-12	46690	12-24 hr	cage rinse	123	15.2	1.87

534006.xls Summary (urine)
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PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 15: [ ] Calibration Samples - Routine Analyses

Sequence	QC	Run # (534006-)	Ref # (534006-)	Target Conc (ng/mL)	Analyzed Conc (ng/mL)	% RE
I6-534006f1 serum	Cal 1	I6-0678	154-2	10.0	10.0	0.20
		I6-0728	154-3	10.0	9.82	-1.9
	Cal 2	I6-0679	154-5	30.0	29.8	-0.82
		I6-0729	154-6	30.0	31.2	4.1
	Cal 3	I6-0680	154-8	100	107	7.2
		I6-0730	154-9	100	104	4.3
	Cal 4	I6-0681	154-11	300	288	-3.9
		I6-0731	154-12	300	252	-16
	Cal 5	I6-0682	154-14	1000	1103	10
		I6-0732	154-15	1000	1066	6.6

534006.xls Cal summary
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PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 15: [ ] Calibration Samples - Routine Analyses

Sequence	QC	Run # (534006-)	Ref # (534006-)	Target Conc (ng/mL)	Analyzed Conc (ng/mL)	% RE
I6-534006g urine	Cal 1	I6-0745	164-1	10.0	11.6	16
		I6-0774	164-2	10.0	10.6	6.0
		I6-0809	164-3	10.0	8.49	-15
	Cal 2	I6-0746	164-4	30.0	27.4	-8.8
		I6-0775	164-5	30.0	27.3	-9.0
		I6-0810	164-6	30.0	27.2	-9.2
	Cal 3	I6-0747	164-7	100	104	4.4
		I6-0776	164-8	100	108	7.6
		I6-0811	164-9	100	101	0.59
	Cal 4	I6-0748	164-10	300	315	4.9
		I6-0777	164-11	300	325	8.5
		I6-0812	164-12	300	294	-2.0
	Cal 5	I6-0749	164-13	1000	974	-2.6
		I6-0778	164-14	1000	1022	2.2
		I6-0813	164-15	1000	961	-3.9

534006.xls Cal summary
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PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 15: [ ] Calibration Samples - Routine Analyses

Sequence	QC	Run # (534006-)	Ref # (534006-)	Target Conc (ng/mL)	Analyzed Conc (ng/mL)	% RE
I6-534006j serum	Cal 1	I6-1034	192-1	10.0	8.67	-13
		I6-1072	192-2	10.0	10.4	4.5
		I6-1117	192-3	10.0	10.5	5.0
	Cal 2	I6-1035	192-4	30.0	26.9	-10
		I6-1073	192-5	30.0	33.7	12
		I6-1118	192-6	30.0	33.3	11
	Cal 3	I6-1036	192-7	100	96.2	-3.8
		I6-1074	192-8	100	99.3	-0.67
		I6-1119	192-9	100	103	3.2
	Cal 4	I6-1037	192-10	300	270	-10
		I6-1075	192-11	300	298	-0.53
		I6-1120	192-12	300	302	0.70
	Cal 5	I6-1038	192-13	500	465	-7.1
		I6-1076	192-14	500	499	-0.11
		I6-1121	192-15	500	517	3.4
	Cal 6	I6-1039	192-16	750	714	-4.9
		I6-1077	192-17	750	763	1.8
		I6-1122	192-18	750	794	5.9
	Cal 7	I6-1040	192-19	1000	963	-3.7
		I6-1078	192-20	1000	1005	0.49
		I6-1123	192-21	1000	1069	6.9

534006.xls Cal summary
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PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 15: [ ] Calibration Samples - Routine Analyses

Sequence	QC	Run # (534006-)	Ref # (534006-)	Target Conc (ng/mL)	Analyzed Conc (ng/mL)	% RE
I6-534006k serum	Cal 1	I6-1140	205-1	10.0	9.64	-3.6
		I6-1162	205-2	10.0	8.91	-11
		I6-1213	205-3	10.0	11.4	14
	Cal 2	I6-1141	205-4	30.0	29.9	-0.28
		I6-1163	205-5	30.0	27.8	-7.4
		I6-1214	205-6	30.0	32.9	10
	Cal 3	I6-1142	205-7	100	99.0	-1.0
		I6-1164	205-8	100	98.6	-1.4
		I6-1215	205-9	100	107	7.2
	Cal 4	I6-1143	205-10	300	287	-4.4
		I6-1165	205-11	300	279	-7.1
		I6-1216	205-12	300	313	4.4
	Cal 5	I6-1144	205-13	500	488	-2.3
		I6-1166	205-14	500	481	-3.7
		I6-1217	205-15	500	530	6.1
	Cal 6	I6-1145	205-16	750	720	-4.0
		I6-1167	205-17	750	718	-4.2
		I6-1218	205-18	750	795	6.0
	Cal 7	I6-1146	205-19	1000	981	-1.9
		I6-1168	205-20	1000	971	-2.9
		I6-1219	205-21	1000	1087	8.7

534006.xls Cal summary
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PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 15: [ ] Calibration Samples - Routine Analyses

Sequence	QC	Run # (534006-)	Ref # (534006-)	Target Conc (ng/mL)	Analyzed Conc (ng/mL)	% RE
I6-53400611 urine	Cal 1	I6-1270	216-1	10.0	10.6	5.8
		I6-1306	216-2	10.0	11.4	14
		I6-1346	216-3	10.0	8.08	-19
	Cal 2	I6-1271	216-4	30.0	28.5	-5.1
		I6-1307	216-5	30.0	29.2	-2.5
		I6-1347	216-6	30.0	31.5	4.8
	Cal 3	I6-1272	216-7	100	101	0.87
		I6-1308	216-8	100	103	3.1
		I6-1348	216-9	100	99.2	-0.82
	Cal 4	I6-1273	216-10	300	321	7.1
		I6-1309	216-11	300	307	2.2
		I6-1349	216-12	300	300	-0.15
	Cal 5	I6-1274	216-13	500	511	2.1
		I6-1310	216-14	500	472	-5.5
		I6-1350	216-15	500	459	-8.1
	Cal 6	I6-1275	216-16	750	732	-2.4
		I6-1311	216-17	750	753	0.46
		I6-1351	216-18	750	693	-7.7
	Cal 7	I6-1276	216-19	1000	1132	13
		I6-1312	216-20	1000	1014	1.4
		I6-1352	216-21	1000	984	-1.6

534006.xls Cal summary
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PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 15: [ ] Calibration Samples - Routine Analyses

Sequence	QC	Run # (534006-)	Ref # (534006-)	Target Conc (ng/mL)	Analyzed Conc (ng/mL)	% RE
I6-534006m urine	Cal 1	I6-1370	227-1	10.0	9.29	-7.1
		I6-1398	227-2	10.0	9.56	-4.4
		I6-1435	227-3	10.0	11.5	15
	Cal 2	*I6-1371	*227-4	30.0	*67.9	*130
		I6-1399	227-5	30.0	28.8	-3.9
		I6-1436	227-6	30.0	27.6	-8.1
	Cal 3	I6-1372	227-7	100	87.8	-12
		I6-1400	227-8	100	106	5.6
		I6-1437	227-9	100	116	16
	Cal 4	I6-1373	227-10	300	312	4.0
		I6-1401	227-11	300	295	-1.8
		I6-1438	227-12	300	291	-3.2
	Cal 5	I6-1374	227-13	500	516	3.3
		I6-1402	227-14	500	536	7.1
		I6-1439	227-15	500	479	-4.1
	Cal 6	I6-1375	227-16	750	757	0.99
		I6-1403	227-17	750	673	-10
		I6-1440	227-18	750	764	1.8
	Cal 7	I6-1376	227-19	1000	919	-8.1
		I6-1404	227-20	1000	1081	8.1
		I6-1441	227-21	1000	1027	2.7

* Sample not included in regression analysis based on test for outliers.

534006.xls Cal summary
Printed: 09/19/07 12:58 PM

PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 15: [ ] Calibration Samples - Routine Analyses

Sequence	QC	Run # (534006-)	Ref # (534006-)	Target Conc (ng/mL)	Analyzed Conc (ng/mL)	% RE
I6-534006o urine	Cal 1	I6-1530	250-1	10.0	9.10	-9.0
		I6-1531	250-2	10.0	10.3	3.5
		I6-1558	250-3	10.0	10.6	6.0
	Cal 2	I6-1532	250-4	30.0	31.2	4.0
		I6-1533	250-5	30.0	27.9	-6.8
		I6-1559	250-6	30.0	31.0	3.2
	Cal 3	I6-1534	250-7	100	89.4	-11
		I6-1535	250-8	100	88.6	-11
		I6-1560	250-9	100	113	13
	Cal 4	I6-1536	250-10	300	279	-7.2
		I6-1561	250-11	300	334	11
		I6-1562	250-12	300	310	3.2
	Cal 5	I6-1537	250-13	500	496	-0.78
		I6-1563	250-14	500	529	5.8
		I6-1564	250-15	500	518	3.6
	Cal 6	I6-1538	250-16	750	703	-6.2
		I6-1565	250-17	750	754	0.49
		I6-1566	250-18	750	745	-0.68
	Cal 7	I6-1539	250-19	1000	960	-4.0
		I6-1567	250-20	1000	1007	0.74
		I6-1568	250-21	1000	1022	2.2

534006.xls Cal summary
Printed: 09/19/07 12:58 PM

PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 16: [ ] Quality Control Samples - Routine Analyses

Sequence	QC	Run # (534006-)	Ref # (534006-)	Target Conc (ng/mL)	Analyzed Conc (ng/mL)	% RE
I6-534006f1 serum	QC1	I6-0684	155-2	30.0	28.0	-6.6
		I6-0723	155-3	30.0	27.4	-8.8
	QC2	I6-0685	155-5	250	217	-13
		I6-0724	155-6	250	225	-9.9
	QC3	I6-0686	155-8	750	823	9.7
		I6-0725	155-9	750	789	5.2
	QC4	I6-0687	155-11	10000	9570	-4.3
		I6-0726	155-12	10000	8753	-12
I6-534006g urine	QC1	I6-0751	165-1	30.0	27.4	-8.7
		I6-0780	165-2	30.0	25.8	-14
		I6-0804	165-3	30.0	28.3	-5.7
	QC2	I6-0752	165-4	250	233	-7.0
		I6-0781	165-5	250	206	-18
		I6-0805	165-6	250	217	-13
	QC3	I6-0753	165-7	750	697	-7.1
		I6-0782	165-8	750	775	3.4
		I6-0806	165-9	750	755	0.69
	QC4	I6-0754	165-10	10000	9516	-4.8
		I6-0783	165-11	10000	9624	-3.8
		I6-0807	165-12	10000	9657	-3.4

534006.xls QC summary
Printed: 09/19/07 12:58 PM

PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 16: [ ] Quality Control Samples - Routine Analyses

Sequence	QC	Run # (534006-)	Ref # (534006-)	Target Conc (ng/mL)	Analyzed Conc (ng/mL)	% RE
I6-534006j serum	QC1	I6-1042	193-1	30.0	28.3	-5.6
		I6-1080	193-2	30.0	30.5	1.8
		I6-1112	193-3	30.0	30.1	0.41
	QC2	I6-1043	193-4	250	236	-5.8
		I6-1081	193-5	250	243	-2.9
		I6-1113	193-6	250	249	-0.45
	QC3	I6-1044	193-7	750	732	-2.4
		I6-1082	193-8	750	735	-1.9
		I6-1114	193-9	750	743	-0.94
	QC4	I6-1045	193-10	30000	27980	-6.7
		I6-1083	193-11	30000	30449	1.5
		I6-1115	193-12	30000	30268	0.89
I6-534006k serum	QC1	I6-1148	206-1	30.0	30.8	2.5
		I6-1170	206-2	30.0	30.6	1.9
		I6-1208	206-3	30.0	32.4	8.2
	QC2	I6-1149	206-4	250	246	-1.7
		I6-1171	206-5	250	242	-3.1
		I6-1209	206-6	250	261	4.3
	QC3	I6-1150	206-7	750	734	-2.1
		I6-1172	206-8	750	747	-0.42
		I6-1210	206-9	750	792	5.5
	QC4	I6-1151	206-10	30000	29723	-0.92
		I6-1173	206-11	30000	28014	-6.6
		I6-1211	206-12	30000	33381	11

534006.xls QC summary
Printed: 09/19/07 12:58 PM

PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 16: [ ] Quality Control Samples - Routine Analyses

Sequence	QC	Run # (534006-)	Ref # (534006-)	Target Conc (ng/mL)	Analyzed Conc (ng/mL)	% RE
I6-53400611 urine	QC1	I6-1278	217-1	30.0	27.9	-7.1
		I6-1314	217-2	30.0	26.9	-10
		I6-1336	217-3	30.0	24.9	-17
	QC2	I6-1279	217-4	250	227	-9.2
		I6-1315	217-5	250	208	-17
		I6-1337	217-6	250	229	-8.6
	QC3	I6-1280	217-7	750	770	2.6
		I6-1316	217-8	750	758	1.1
		I6-1338	217-9	750	746	-0.54
	QC4	I6-1281	217-10	30000	28222	-5.9
		I6-1317	217-11	30000	25817	-14
		I6-1339	217-12	30000	26170	-13
cage rinse	QC1	I6-1283	219-1	30.0	31.2	3.9
		I6-1319	219-2	30.0	29.4	-2.0
		I6-1341	219-3	30.0	29.9	-0.24
	QC2	I6-1284	219-4	250	240	-3.9
		I6-1320	219-5	250	232	-7.1
		I6-1342	219-6	250	253	1.2
	QC3	I6-1285	219-7	750	750	0.062
		I6-1321	219-8	750	783	4.4
		I6-1343	219-9	750	783	4.4
	QC4	I6-1286	219-10	30000	27523	-8.3
		I6-1322	219-11	30000	28519	-4.9
		I6-1344	219-12	30000	27956	-6.8

534006.xls QC summary
Printed: 09/19/07 12:58 PM

PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

Table 16: [ ] Quality Control Samples - Routine Analyses

Sequence	QC	Run # (534006-)	Ref # (534006-)	Target Conc (ng/mL)	Analyzed Conc (ng/mL)	% RE
I6-534006m urine	QC1	I6-1378	228-1	30.0	28.8	-3.9
		I6-1406	228-2	30.0	28.3	-5.8
		I6-1430	228-3	30.0	27.5	-8.3
	QC2	I6-1379	228-4	250	225	-10
		I6-1407	228-5	250	207	-17
		I6-1431	228-6	250	265	6.1
	QC3	I6-1380	228-7	750	645	-14
		I6-1408	228-8	750	683	-8.9
		I6-1432	228-9	750	818	9.1
	QC4	I6-1381	228-10	150000	173620	16
		I6-1409	228-11	150000	164740	9.8
		I6-1433	228-12	150000	160180	6.8
I6-534006o urine	QC1	I6-1541	251-1	30.0	30.1	0.20
		I6-1542	251-2	30.0	26.9	-10
		I6-1551	251-3	30.0	27.3	-9.0
	QC2	I6-1543	251-4	250	253	1.1
		I6-1544	251-5	250	258	3.3
		I6-1552	251-6	250	224	-10
	QC3	I6-1545	251-7	750	807	7.6
		I6-1553	251-8	750	736	-1.9
		I6-1554	251-9	750	732	-2.4
	QC4	I6-1546	251-10	30000	29442	-1.9
		I6-1555	251-11	30000	28811	-4.0
		I6-1556	251-12	30000	32312	7.7

534006.xls QC summary
Printed: 09/19/07 12:58 PM

FIGURES 1 - 57

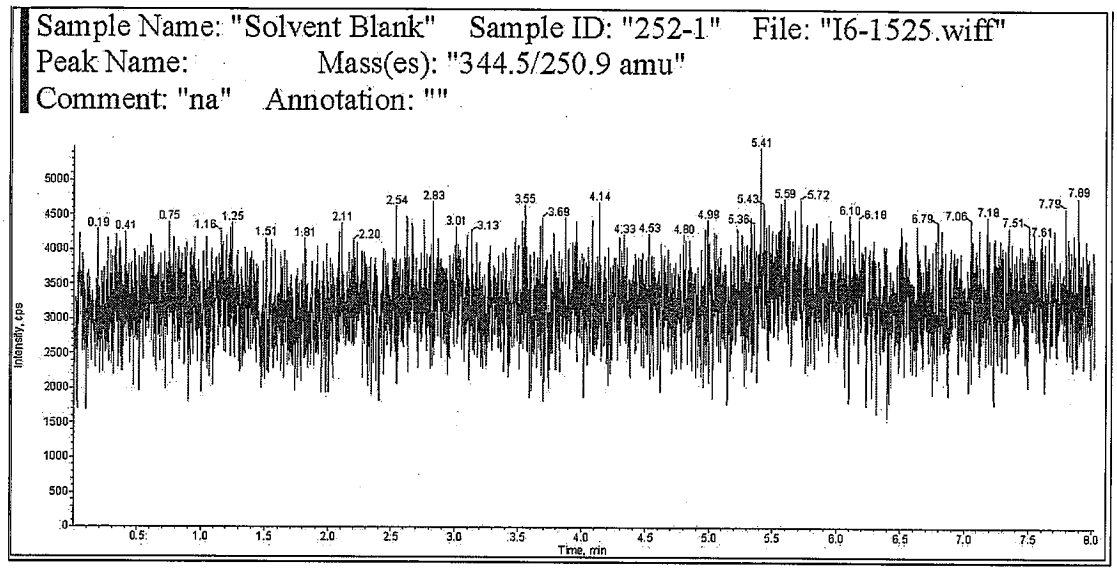

Figure 1: Representative Chromatogram Of A Solvent Blank

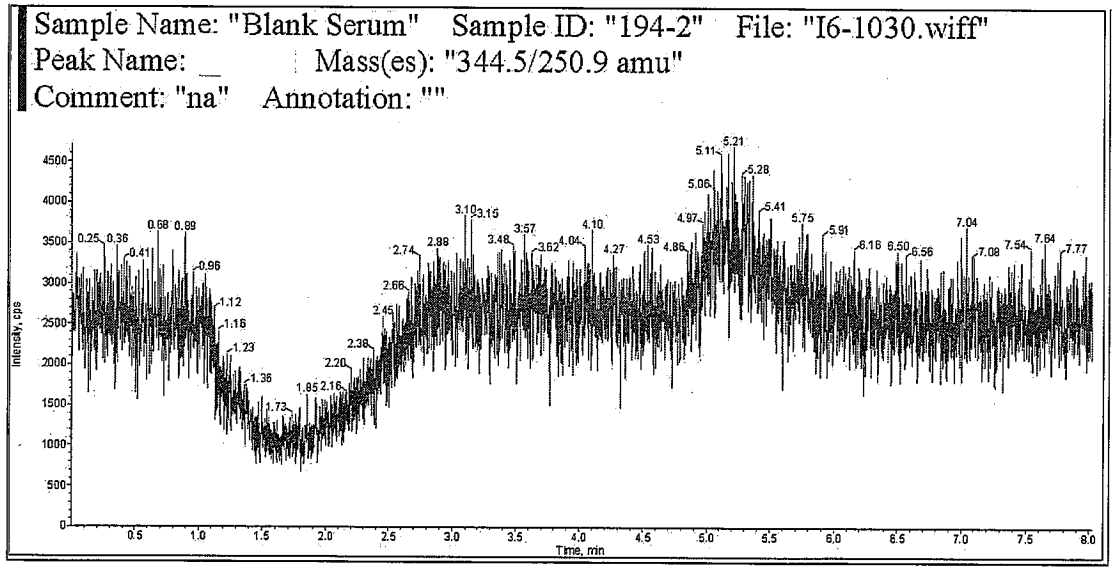

Figure 2: Representative Chromatogram Of A Processed Blank Rat Serum Sample

ATTACHMENT I

Supporting Data

Table A-1: I8-534006a Data

Note:
Validation session 1

Study Record Page: 82b

Results Path: \\Lcmsp03\sciexdata\Projects\534006\Bio\Results\I8-534006a1.r
Results Name: I8-534006a1.rdb

	File Name	Sample ID	Sample Name	Sample Type	Analyte Peak Name	Use Record	Analyte Concentration (ng/mL)	Dilution Factor	Calculated Concentration (ng/mL)
1	I8-534006a\I8-0001.wiff	72-7	Sys Suit	Unknown			N/A	1.00	No Intercept
2	I8-534006a\I8-0002.wiff	72-7	Sys Suit	Unknown			N/A	1.00	No Intercept
3	I8-534006a\I8-0003.wiff	72-7	Sys Suit	Unknown			N/A	1.00	No Intercept
4	I8-534006a\I8-0004.wiff	72-7	Sys Suit	Unknown			N/A	1.00	No Intercept
5	I8-534006a\I8-0005.wiff	71-1	Diluent	Unknown			N/A	1.00	No Peak
6	I8-534006a\I8-0006.wiff	76-1	Solvent Blank	Unknown			N/A	1.00	No Peak
7	I8-534006a\I8-0007.wiff	76-2	Serum Blank	Unknown			N/A	1.00	No Peak
8	I8-534006a\I8-0008.wiff	76-3	Serum Blank	Unknown			N/A	1.00	2.0660
9	I8-534006a\I8-0009.wiff	76-4	Serum Blank	Unknown			N/A	1.00	No Peak
10	I8-534006a\I8-0010.wiff	71-1	Diluent	Unknown			N/A	1.00	No Peak
11	I8-534006a\I8-0011.wiff	74-1	C 10	Standard		☒	10.000	1.00	10.429
12	I8-534006a\I8-0012.wiff	74-2	C 10	Standard		☒	10.000	1.00	10.445
13	I8-534006a\I8-0013.wiff	74-3	C 10	Standard		☒	10.000	1.00	9.4050
14	I8-534006a\I8-0014.wiff	74-4	C 30	Standard		☒	30.000	1.00	28.505
15	I8-534006a\I8-0015.wiff	74-5	C 30	Standard		☒	30.000	1.00	28.841
16	I8-534006a\I8-0016.wiff	74-6	C 30	Standard		☒	30.000	1.00	29.016
17	I8-534006a\I8-0017.wiff	74-7	C 100	Standard		☒	100.00	1.00	103.90
18	I8-534006a\I8-0018.wiff	74-8	C 100	Standard		☒	100.00	1.00	105.07
19	I8-534006a\I8-0019.wiff	74-9	C 100	Standard		☒	100.00	1.00	105.35
20	I8-534006a\I8-0020.wiff	74-10	C 300	Standard		☒	300.00	1.00	300.75
21	I8-534006a\I8-0021.wiff	74-11	C 300	Standard		☒	300.00	1.00	296.48
22	I8-534006a\I8-0022.wiff	74-12	C 300	Standard		☒	300.00	1.00	285.82
23	I8-534006a\I8-0023.wiff	74-13	C 1000	Standard		☒	1000.0	1.00	1015.0
24	I8-534006a\I8-0024.wiff	74-14	C 1000	Standard		☒	1000.0	1.00	989.69
25	I8-534006a\I8-0025.wiff	74-15	C 1000	Standard		☒	1000.0	1.00	1003.0
26	I8-534006a\I8-0026.wiff	74-16	C 3000	Standard		☐	3000.0	1.00	No Intercept
27	I8-534006a\I8-0027.wiff	74-17	C 3000	Standard		☐	3000.0	1.00	No Intercept
28	I8-534006a\I8-0028.wiff	74-18	C 3000	Standard		☐	3000.0	1.00	No Intercept
29	I8-534006a\I8-0029.wiff	71-1	Diluent	Unknown			N/A	1.00	No Peak

Printing Date: Wednesday, April 18, 2007
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Operator: Shelley Hollar
Analyst Version: 1.4.2

Results Path: \\Lcmsp03\sciexdata\Projects\534006\Bio\Results\I8-534006a1.r
Results Name: I8-534006a1.rdb

	File Name	Sample ID	Sample Name	Sample Type	Analyte Peak Name	Use Record	Analyte Concentration (ng/mL)	Dilution Factor	Calculated Concentration (ng/mL)
30	I8-534006a\I8-0030.wiff	75-1	QC 30	Quality Control		☒	30.000	1.00	28.077
31	I8-534006a\I8-0031.wiff	75-2	QC 30	Quality Control		☒	30.000	1.00	28.688
32	I8-534006a\I8-0032.wiff	75-3	QC 30	Quality Control		☒	30.000	1.00	29.159
33	I8-534006a\I8-0033.wiff	75-4	QC 250	Quality Control		☒	250.00	1.00	237.95
34	I8-534006a\I8-0034.wiff	75-5	QC 250	Quality Control		☒	250.00	1.00	240.98
35	I8-534006a\I8-0035.wiff	75-6	QC 250	Quality Control		☒	250.00	1.00	244.27
36	I8-534006a\I8-0036.wiff	75-7	QC 750	Quality Control		☒	750.00	1.00	713.99
37	I8-534006a\I8-0037.wiff	75-8	QC 750	Quality Control		☒	750.00	1.00	723.21
38	I8-534006a\I8-0038.wiff	75-9	QC 750	Quality Control		☒	750.00	1.00	723.44
39	I8-534006a\I8-0039.wiff	75-10	QC 2500	Quality Control		☒	2500.0	1.00	No Intercept
40	I8-534006a\I8-0040.wiff	75-11	QC 2500	Quality Control		☒	2500.0	1.00	No Intercept
41	I8-534006a\I8-0041.wiff	75-12	QC 2500	Quality Control		☒	2500.0	1.00	No Intercept
42	I8-534006a\I8-0042.wiff	75-13	QC 10000	Quality Control		☒	10000.	20.0	9425.1
43	I8-534006a\I8-0043.wiff	75-14	QC 10000	Quality Control		☒	10000.	20.0	9383.7
44	I8-534006a\I8-0044.wiff	75-15	QC 10000	Quality Control		☒	10000.	20.0	9490.1

Printing Date: Wednesday, April 18, 2007
Printing Time: 8:10:35 AM

Operator: Shelley Hollar
Analyst Version: 1.4.2

	File Name	%RE	Analyte Peak Area (counts)	Analyte Retention Time (min)	Analyte Integration Type	Record Modified	Sample Annotation
1	I8-534006a\I8-0001.wiff	#BAD!	3.03e+007	3.98	Base To Base	☒	
2	I8-534006a\I8-0002.wiff	#BAD!	3.23e+007	3.71	Base To Base	☐	
3	I8-534006a\I8-0003.wiff	#BAD!	3.31e+007	3.66	Base To Base	☐	
4	I8-534006a\I8-0004.wiff	#BAD!	3.34e+007	3.65	Base To Base	☐	
5	I8-534006a\I8-0005.wiff	N/A	0.00e+000	0.00	No Peak	☐	
6	I8-534006a\I8-0006.wiff	N/A	0.00e+000	0.00	No Peak	☒	
7	I8-534006a\I8-0007.wiff	N/A	0.00e+000	0.00	No Peak	☒	
8	I8-534006a\I8-0008.wiff	N/A	2.94e+004	3.55	Base To Base	☐	
9	I8-534006a\I8-0009.wiff	N/A	0.00e+000	0.00	No Peak	☒	
10	I8-534006a\I8-0010.wiff	N/A	0.00e+000	0.00	No Peak	☐	
11	I8-534006a\I8-0011.wiff	4.3	1.63e+005	3.52	Base To Base	☐	
12	I8-534006a\I8-0012.wiff	4.5	1.64e+005	3.52	Base To Base	☐	
13	I8-534006a\I8-0013.wiff	-5.9	1.47e+005	3.51	Base To Base	☐	
14	I8-534006a\I8-0014.wiff	-5.0	4.51e+005	3.49	Base To Base	☐	
15	I8-534006a\I8-0015.wiff	-3.9	4.57e+005	3.50	Base To Base	☐	
16	I8-534006a\I8-0016.wiff	-3.3	4.59e+005	3.50	Base To Base	☐	
17	I8-534006a\I8-0017.wiff	3.9	1.63e+006	3.48	Base To Base	☐	
18	I8-534006a\I8-0018.wiff	5.1	1.65e+006	3.51	Base To Base	☐	
19	I8-534006a\I8-0019.wiff	5.3	1.65e+006	3.46	Base To Base	☐	
20	I8-534006a\I8-0020.wiff	0.25	4.54e+006	3.45	Base To Base	☐	
21	I8-534006a\I8-0021.wiff	-1.2	4.48e+006	3.45	Base To Base	☐	
22	I8-534006a\I8-0022.wiff	-4.7	4.32e+006	3.43	Base To Base	☐	
23	I8-534006a\I8-0023.wiff	1.5	1.30e+007	3.43	Base To Base	☐	
24	I8-534006a\I8-0024.wiff	-1.0	1.28e+007	3.42	Base To Base	☐	
25	I8-534006a\I8-0025.wiff	0.30	1.29e+007	3.41	Base To Base	☐	
26	I8-534006a\I8-0026.wiff	#BAD!	2.89e+007	3.42	Base To Base	☐	
27	I8-534006a\I8-0027.wiff	#BAD!	2.93e+007	3.39	Base To Base	☐	
28	I8-534006a\I8-0028.wiff	#BAD!	2.97e+007	3.38	Base To Base	☐	
29	I8-534006a\I8-0029.wiff	N/A	0.00e+000	0.00	No Peak	☐	

Results Path: \\Lcmsp03\sciexdata\Projects\534006\Bio\Results\I8-534006a1.r
Results Name: I8-534006a1.rdb

	File Name	%RE	Analyte Peak Area (counts)	Analyte Retention Time (min)	Analyte Integration Type	Record Modified	Sample Annotation
30	I8-534006a\I8-0030.wiff	-6.4	4.45e+005	3.37	Base To Base	☐	
31	I8-534006a\I8-0031.wiff	-4.4	4.54e+005	3.35	Base To Base	☐	
32	I8-534006a\I8-0032.wiff	-2.8	4.62e+005	3.36	Base To Base	☐	
33	I8-534006a\I8-0033.wiff	-4.8	3.64e+006	3.34	Base To Base	☐	
34	I8-534006a\I8-0034.wiff	-3.6	3.68e+006	3.35	Base To Base	☐	
35	I8-534006a\I8-0035.wiff	-2.3	3.73e+006	3.35	Base To Base	☐	
36	I8-534006a\I8-0036.wiff	-4.8	9.83e+006	3.36	Base To Base	☐	
37	I8-534006a\I8-0037.wiff	-3.6	9.94e+006	3.37	Base To Base	☐	
38	I8-534006a\I8-0038.wiff	-3.5	9.94e+006	3.35	Base To Base	☐	
39	I8-534006a\I8-0039.wiff	#BAD!	2.44e+007	3.33	Base To Base	☐	
40	I8-534006a\I8-0040.wiff	#BAD!	2.40e+007	3.34	Base To Base	☐	
41	I8-534006a\I8-0041.wiff	#BAD!	2.46e+007	3.35	Base To Base	☐	
42	I8-534006a\I8-0042.wiff	-5.7	6.85e+006	3.34	Base To Base	☐	
43	I8-534006a\I8-0043.wiff	-6.2	6.83e+006	3.32	Base To Base	☐	
44	I8-534006a\I8-0044.wiff	-5.1	6.90e+006	3.31	Base To Base	☐	

Printing Date: Wednesday, April 18, 2007
Printing Time: 8:10:35 AM

Operator: Shelley Hollar
Analyst Version: 1.4.2

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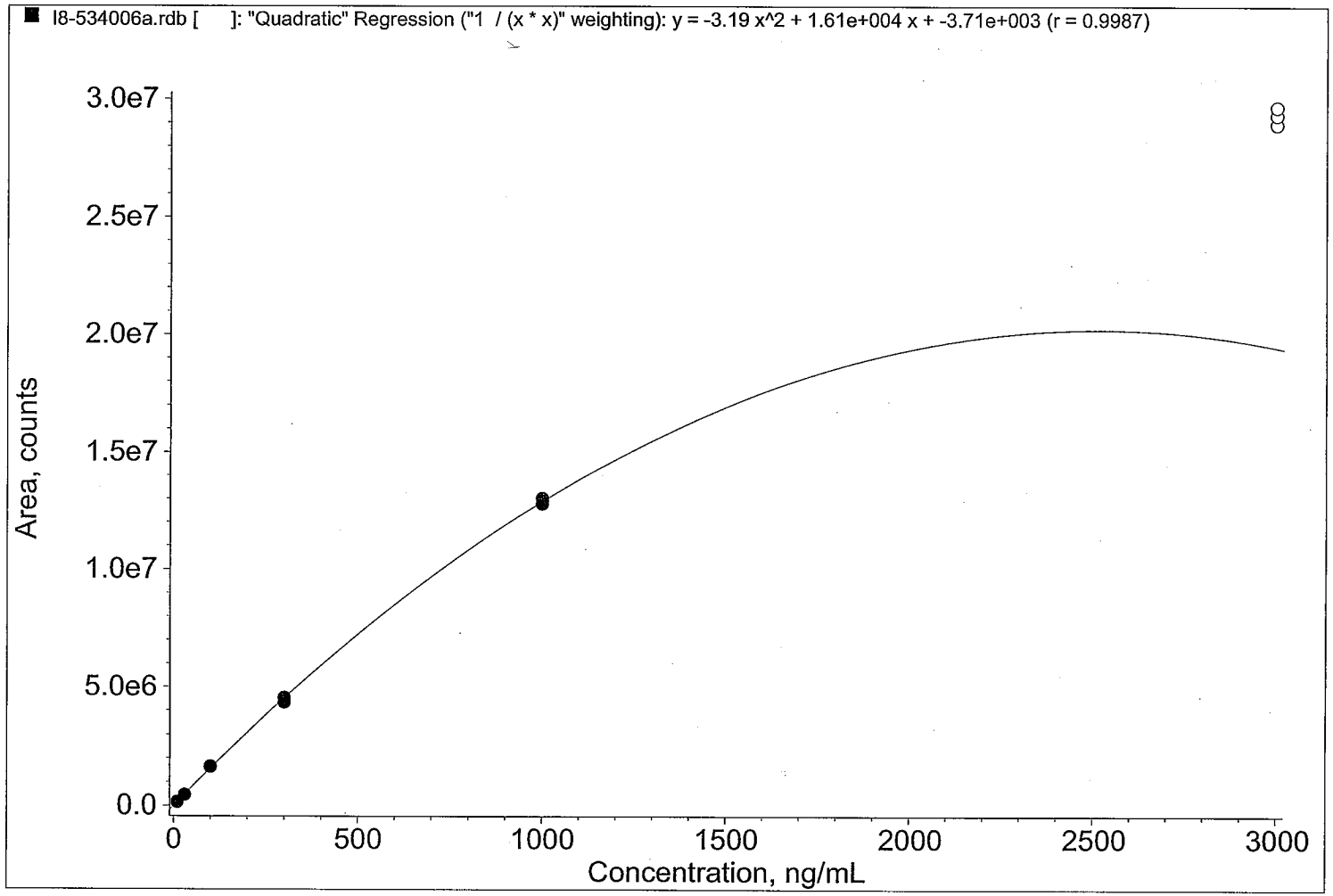
Results Name: I8-534006a1.rdb



Printing Date: Thursday, March 15, 2007
Printing Time: 10:04:12 AM

Operator: Shelley Hollar
Analyst Version: 1.4.2

Table A-2: I8-534006b Data

Note:
Validation session 2

Study Record Page: 82c

Results Path: \\Lcmsp03\sciexdata\Projects\534006\Bio\Results\I8-534006b1.r
Results Name: I8-534006b1.rdb

	File Name	Sample ID	Sample Name	Sample Type	Analyte Peak Name	Use Record	Analyte Concentration (ng/mL)	Dilution Factor	Calculated Concentration (ng/mL)
1	I8-534006b\I8-0045.wiff	71-1	Diluent	Unknown			N/A	1.00	No Peak
2	I8-534006b\I8-0045.wiff	71-1	Diluent	Unknown			N/A	1.00	No Peak
3	I8-534006b\I8-0045.wiff	71-1	Diluent	Unknown			N/A	1.00	No Peak
4	I8-534006b\I8-0046.wiff	81-1	Solvent Blank	Unknown			N/A	1.00	< 0
5	I8-534006b\I8-0047.wiff	81-2	Serum Blank	Unknown			N/A	1.00	0.17030
6	I8-534006b\I8-0048.wiff	81-3	Serum Blank	Unknown			N/A	1.00	0.69883
7	I8-534006b\I8-0049.wiff	81-4	Serum Blank	Unknown			N/A	1.00	1.0433
8	I8-534006b\I8-0050.wiff	71-1	Diluent	Unknown			N/A	1.00	No Peak
9	I8-534006b\I8-0051.wiff	79-1	C 10	Standard		☒	10.000	1.00	9.9542
10	I8-534006b\I8-0052.wiff	79-2	C 10	Standard		☒	10.000	1.00	10.325
11	I8-534006b\I8-0053.wiff	79-3	C 10	Standard		☒	10.000	1.00	9.7624
12	I8-534006b\I8-0054.wiff	79-4	C 30	Standard		☐	30.000	1.00	49.371
13	I8-534006b\I8-0055.wiff	79-5	C 30	Standard		☒	30.000	1.00	29.881
14	I8-534006b\I8-0056.wiff	79-6	C 30	Standard		☒	30.000	1.00	30.016
15	I8-534006b\I8-0057.wiff	79-7	C 100	Standard		☒	100.00	1.00	97.883
16	I8-534006b\I8-0058.wiff	79-8	C 100	Standard		☒	100.00	1.00	98.277
17	I8-534006b\I8-0059.wiff	79-9	C 100	Standard		☒	100.00	1.00	98.609
18	I8-534006b\I8-0060.wiff	79-10	C 300	Standard		☒	300.00	1.00	317.89
19	I8-534006b\I8-0061.wiff	79-11	C 300	Standard		☒	300.00	1.00	304.62
20	I8-534006b\I8-0062.wiff	79-12	C 300	Standard		☒	300.00	1.00	299.33
21	I8-534006b\I8-0063.wiff	79-13	C 1000	Standard		☒	1000.0	1.00	974.30
22	I8-534006b\I8-0064.wiff	79-14	C 1000	Standard		☒	1000.0	1.00	982.44
23	I8-534006b\I8-0065.wiff	79-15	C 1000	Standard		☒	1000.0	1.00	1019.5
24	I8-534006b\I8-0066.wiff	79-16	C 3000	Standard		☐	3000.0	1.00	No Intercept
25	I8-534006b\I8-0067.wiff	79-17	C 3000	Standard		☐	3000.0	1.00	No Intercept
26	I8-534006b\I8-0068.wiff	79-18	C 3000	Standard		☐	3000.0	1.00	No Intercept
27	I8-534006b\I8-0069.wiff	71-1	Diluent	Unknown			N/A	1.00	No Peak
28	I8-534006b\I8-0070.wiff	80-1	QC 30	Quality Control		☒	30.000	1.00	31.268
29	I8-534006b\I8-0071.wiff	80-2	QC 30	Quality Control		☒	30.000	1.00	29.209

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Results Path: \\Lcmsp03\sciexdata\Projects\534006\Bio\Results\I8-534006b1.r
Results Name: I8-534006b1.rdb

	File Name	Sample ID	Sample Name	Sample Type	Analyte Peak Name	Use Record	Analyte Concentration (ng/mL)	Dilution Factor	Calculated Concentration (ng/mL)
30	I8-534006b\I8-0072.wiff	80-3	QC 30	Quality Control		☒	30.000	1.00	28.118
31	I8-534006b\I8-0073.wiff	80-4	QC 250	Quality Control		☒	250.00	1.00	238.79
32	I8-534006b\I8-0074.wiff	80-5	QC 250	Quality Control		☒	250.00	1.00	241.12
33	I8-534006b\I8-0075.wiff	80-6	QC 250	Quality Control		☒	250.00	1.00	247.64
34	I8-534006b\I8-0076.wiff	80-7	QC 750	Quality Control		☒	750.00	1.00	748.10
35	I8-534006b\I8-0077.wiff	80-8	QC 750	Quality Control		☒	750.00	1.00	753.89
36	I8-534006b\I8-0078.wiff	80-9	QC 750	Quality Control		☒	750.00	1.00	746.68
37	I8-534006b\I8-0079.wiff	80-10	QC 2500	Quality Control		☐	2500.0	1.00	No Intercept
38	I8-534006b\I8-0080.wiff	80-11	QC 2500	Quality Control		☐	2500.0	1.00	No Intercept
39	I8-534006b\I8-0081.wiff	80-12	QC 2500	Quality Control		☐	2500.0	1.00	No Intercept
40	I8-534006b\I8-0082.wiff	80-13	QC 10000	Quality Control		☒	10000.	20.0	9708.7
41	I8-534006b\I8-0083.wiff	80-14	QC 10000	Quality Control		☒	10000.	20.0	9684.9
42	I8-534006b\I8-0084.wiff	80-15	QC 10000	Quality Control		☒	10000.	20.0	9625.8

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Operator: Shelley Hollar
Analyst Version: 1.4.2

Results Path: \\Lcmsp03\sciexdata\Projects\534006\Bio\Results\I8-534006b1.r
Results Name: I8-534006b1.rdb

	File Name	%RE	Analyte Peak Area (counts)	Analyte Retention Time (min)	Analyte Integration Type	Record Modified	Sample Annotation
1	I8-534006b\I8-0045.wiff	N/A	0.00e+000	0.00	No Peak	☐	
2	I8-534006b\I8-0045.wiff	N/A	0.00e+000	0.00	No Peak	☐	
3	I8-534006b\I8-0045.wiff	N/A	0.00e+000	0.00	No Peak	☐	
4	I8-534006b\I8-0046.wiff	#BAD!	1.27e+003	3.12	Base To Base	☐	
5	I8-534006b\I8-0047.wiff	N/A	1.10e+004	3.29	Base To Base	☐	
6	I8-534006b\I8-0048.wiff	N/A	2.04e+004	3.33	Base To Base	☐	
7	I8-534006b\I8-0049.wiff	N/A	2.65e+004	3.32	Base To Base	☐	
8	I8-534006b\I8-0050.wiff	N/A	0.00e+000	0.00	No Peak	☐	
9	I8-534006b\I8-0051.wiff	-0.46	1.84e+005	3.28	Base To Base	☐	
10	I8-534006b\I8-0052.wiff	3.3	1.91e+005	3.30	Base To Base	☐	
11	I8-534006b\I8-0053.wiff	-2.4	1.81e+005	3.28	Base To Base	☐	
12	I8-534006b\I8-0054.wiff	65.	8.76e+005	3.28	Base To Base	☐	
13	I8-534006b\I8-0055.wiff	-0.40	5.36e+005	3.28	Base To Base	☐	
14	I8-534006b\I8-0056.wiff	0.053	5.38e+005	3.28	Base To Base	☐	
15	I8-534006b\I8-0057.wiff	-2.1	1.71e+006	3.27	Base To Base	☐	
16	I8-534006b\I8-0058.wiff	-1.7	1.72e+006	3.29	Base To Base	☐	
17	I8-534006b\I8-0059.wiff	-1.4	1.72e+006	3.28	Base To Base	☐	
18	I8-534006b\I8-0060.wiff	6.0	5.27e+006	3.28	Base To Base	☐	
19	I8-534006b\I8-0061.wiff	1.5	5.07e+006	3.29	Base To Base	☐	
20	I8-534006b\I8-0062.wiff	-0.22	4.99e+006	3.27	Base To Base	☐	
21	I8-534006b\I8-0063.wiff	-2.6	1.37e+007	3.30	Base To Base	☐	
22	I8-534006b\I8-0064.wiff	-1.8	1.38e+007	3.25	Base To Base	☐	
23	I8-534006b\I8-0065.wiff	1.9	1.42e+007	3.27	Base To Base	☐	
24	I8-534006b\I8-0066.wiff	#BAD!	3.15e+007	3.27	Base To Base	☐	
25	I8-534006b\I8-0067.wiff	#BAD!	3.12e+007	3.27	Base To Base	☐	
26	I8-534006b\I8-0068.wiff	#BAD!	3.17e+007	3.27	Base To Base	☐	
27	I8-534006b\I8-0069.wiff	N/A	0.00e+000	0.00	No Peak	☐	
28	I8-534006b\I8-0070.wiff	4.2	5.60e+005	3.27	Base To Base	☐	
29	I8-534006b\I8-0071.wiff	-2.6	5.24e+005	3.25	Base To Base	☐	

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Results Path: \\Lcmsp03\sciexdata\Projects\534006\Bio\Results\I8-534006b1.r
Results Name: I8-534006b1.rdb

	File Name	%RE	Analyte Peak Area (counts)	Analyte Retention Time (min)	Analyte Integration Type	Record Modified	Sample Annotation
30	I8-534006b\I8-0072.wiff	-6.3	5.05e+005	3.26	Base To Base	☐	
31	I8-534006b\I8-0073.wiff	-4.5	4.04e+006	3.26	Base To Base	☐	
32	I8-534006b\I8-0074.wiff	-3.6	4.07e+006	3.26	Base To Base	☐	
33	I8-534006b\I8-0075.wiff	-0.94	4.18e+006	3.25	Base To Base	☐	
34	I8-534006b\I8-0076.wiff	-0.25	1.12e+007	3.24	Base To Base	☐	
35	I8-534006b\I8-0077.wiff	0.52	1.12e+007	3.25	Base To Base	☐	
36	I8-534006b\I8-0078.wiff	-0.44	1.12e+007	3.24	Base To Base	☐	
37	I8-534006b\I8-0079.wiff	#BAD!	2.70e+007	3.23	Base To Base	☐	
38	I8-534006b\I8-0080.wiff	#BAD!	2.68e+007	3.25	Base To Base	☐	
39	I8-534006b\I8-0081.wiff	#BAD!	2.66e+007	3.25	Base To Base	☐	
40	I8-534006b\I8-0082.wiff	-2.9	7.74e+006	3.24	Base To Base	☐	
41	I8-534006b\I8-0083.wiff	-3.2	7.72e+006	3.25	Base To Base	☐	
42	I8-534006b\I8-0084.wiff	-3.7	7.68e+006	3.24	Base To Base	☐	

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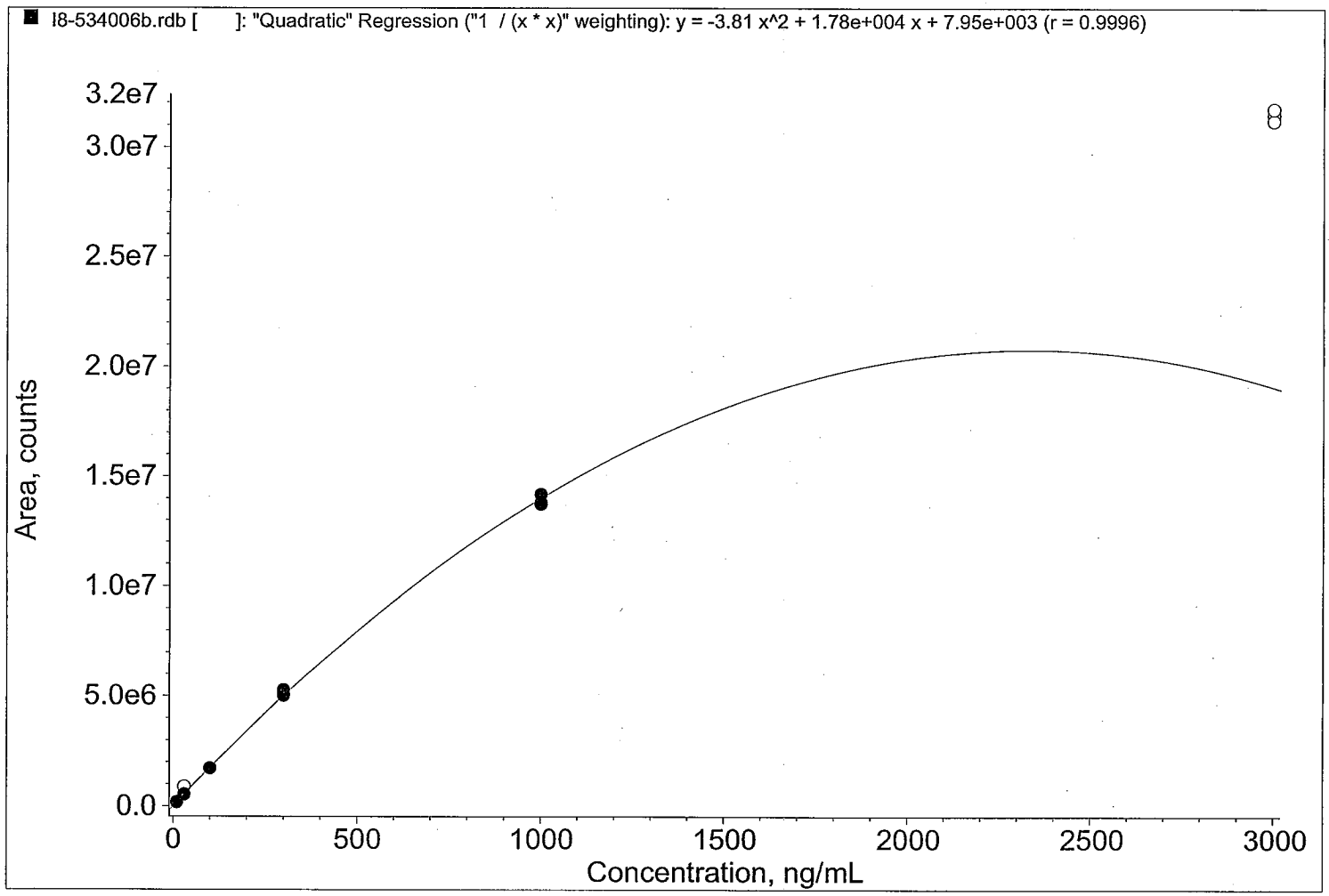
Results Path: \\Lcmsp03\sciexdata\Projects\534006\Bio\Results\I8-534006b1.r
Results Name: I8-534006b1.rdb



Printing Date: Thursday, March 15, 2007
Printing Time: 10:09:50 AM

Operator: Shelley Hollar
Analyst Version: 1.4.2

Table A-3: I8-534006g Data

Note:
Validation session 3

Study Record Page: 129b

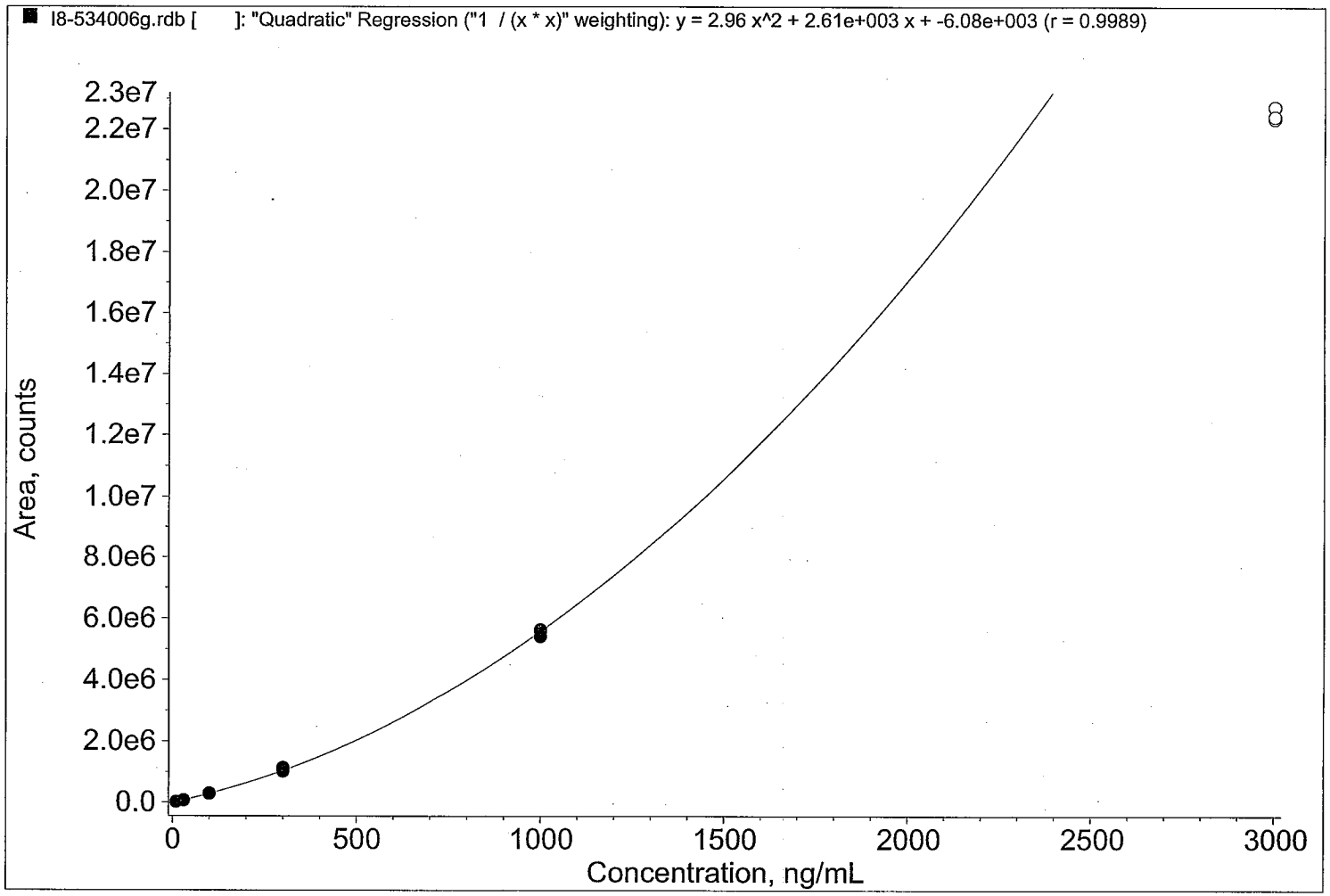
Results Path: \\Lcmsp03\sciexdata\Projects\534006\Bio\Results\I8-534006gr.r
Results Name: I8-534006gr.rdb

	File Name	Sample ID	Sample Name	Sample Type	Analyte Peak Name	Use Record	Analyte Concentration (ng/mL)	Dilution Factor	Calculated Concentration (ng/mL)	%RE	Analyte Peak Area (counts)	Analyte Retention Time (min)	Analyte Integration Type	Record Modified	Sample Annotation
1	I8-534006g\I8-0257.wiff	115-8	Sys Suit	Unknown			N/A	1.00	1995.8	N/A	1.70e+007	3.22	Valley	☐	
2	I8-534006g\I8-0258.wiff	115-8	Sys Suit	Unknown			N/A	1.00	2027.8	N/A	1.75e+007	3.22	Valley	☐	
3	I8-534006g\I8-0259.wiff	115-8	Sys Suit	Unknown			N/A	1.00	2853.0	N/A	3.15e+007	3.21	Valley	☐	
4	I8-534006g\I8-0260.wiff	115-8	Sys Suit	Unknown			N/A	1.00	2837.1	N/A	3.12e+007	3.18	Valley	☐	
5	I8-534006g\I8-0261.wiff	115-8	Sys Suit	Unknown			N/A	1.00	2237.1	N/A	2.07e+007	3.26	Valley	☐	
6	I8-534006g\I8-0262.wiff	115-8	Sys Suit	Unknown			N/A	1.00	2141.0	N/A	1.92e+007	3.23	Valley	☐	
7	I8-534006g\I8-0263.wiff	115-8	Sys Suit	Unknown			N/A	1.00	3437.8	N/A	4.40e+007	3.28	Base To Base	☐	
8	I8-534006g\I8-0264.wiff	115-8	Sys Suit	Unknown			N/A	1.00	2106.8	N/A	1.86e+007	3.15	Valley	☐	
9	I8-534006g\I8-0265.wiff	115-8	Sys Suit	Unknown			N/A	1.00	2375.5	N/A	2.29e+007	3.13	Valley	☐	
10	I8-534006g\I8-0266.wiff	115-8	Sys Suit	Unknown			N/A	1.00	1370.4	N/A	9.13e+006	3.16	Base To Base	☐	
11	I8-534006g\I8-0267.wiff	115-8	Sys Suit	Unknown			N/A	1.00	1354.9	N/A	8.97e+006	3.15	Base To Base	☐	
12	I8-534006g\I8-0268.wiff	115-8	Sys Suit	Unknown			N/A	1.00	1357.9	N/A	9.00e+006	3.15	Base To Base	☐	
13	I8-534006g\I8-0269.wiff	115-8	Sys Suit	Unknown			N/A	1.00	1361.6	N/A	9.04e+006	3.17	Base To Base	☐	
14	I8-534006g\I8-0270.wiff	114-1	Diluent	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
15	I8-534006g\I8-0271.wiff	119-1	Solvent Blank	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
16	I8-534006g\I8-0272.wiff	119-2	Serum Blank	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
17	I8-534006g\I8-0273.wiff	119-3	Serum Blank	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
18	I8-534006g\I8-0274.wiff	119-4	Serum Blank	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
19	I8-534006g\I8-0275.wiff	114-1	Diluent	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
20	I8-534006g\I8-0276.wiff	117-1	C 10	Standard		☒	10.000	1.00	10.100	1.0	2.06e+004	3.19	Base To Base	☐	
21	I8-534006g\I8-0277.wiff	117-2	C 10	Standard		☒	10.000	1.00	10.138	1.4	2.07e+004	3.12	Base To Base	☐	
22	I8-534006g\I8-0278.wiff	117-3	C 10	Standard		☒	10.000	1.00	10.395	4.0	2.14e+004	3.14	Base To Base	☐	
23	I8-534006g\I8-0279.wiff	117-4	C 30	Standard		☒	30.000	1.00	27.263	-9.1	6.73e+004	3.13	Base To Base	☐	
24	I8-534006g\I8-0280.wiff	117-5	C 30	Standard		☒	30.000	1.00	29.616	-1.3	7.39e+004	3.12	Base To Base	☐	
25	I8-534006g\I8-0281.wiff	117-6	C 30	Standard		☒	30.000	1.00	26.707	-11.	6.58e+004	3.13	Base To Base	☐	
26	I8-534006g\I8-0282.wiff	117-7	C 100	Standard		☒	100.00	1.00	102.86	2.9	2.94e+005	3.13	Base To Base	☐	
27	I8-534006g\I8-0283.wiff	117-8	C 100	Standard		☒	100.00	1.00	99.069	-0.93	2.82e+005	3.13	Base To Base	☐	
28	I8-534006g\I8-0284.wiff	117-9	C 100	Standard		☒	100.00	1.00	103.84	3.8	2.97e+005	3.12	Base To Base	☐	
29	I8-534006g\I8-0285.wiff	117-10	C 300	Standard		☒	300.00	1.00	321.99	7.3	1.14e+006	3.14	Base To Base	☐	
30	I8-534006g\I8-0286.wiff	117-11	C 300	Standard		☒	300.00	1.00	307.89	2.6	1.08e+006	3.13	Base To Base	☐	
31	I8-534006g\I8-0287.wiff	117-12	C 300	Standard		☒	300.00	1.00	293.38	-2.2	1.01e+006	3.14	Base To Base	☐	
32	I8-534006g\I8-0288.wiff	117-13	C 1000	Standard		☒	1000.0	1.00	1006.7	0.67	5.62e+006	3.14	Base To Base	☐	
33	I8-534006g\I8-0289.wiff	117-14	C 1000	Standard		☒	1000.0	1.00	1000.1	0.013	5.57e+006	3.14	Base To Base	☐	
34	I8-534006g\I8-0290.wiff	117-15	C 1000	Standard		☒	1000.0	1.00	980.56	-1.9	5.40e+006	3.13	Base To Base	☐	
35	I8-534006g\I8-0291.wiff	117-16	C 3000	Standard		☐	3000.0	1.00	2365.1	-21.	2.27e+007	3.12	Base To Base	☐	
36	I8-534006g\I8-0292.wiff	117-17	C 3000	Standard		☐	3000.0	1.00	2342.0	-22.	2.23e+007	3.14	Base To Base	☐	
37	I8-534006g\I8-0293.wiff	117-18	C 3000	Standard		☐	3000.0	1.00	2345.8	-22.	2.24e+007	3.13	Base To Base	☐	
38	I8-534006g\I8-0294.wiff	114-1	Diluent	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
39	I8-534006g\I8-0295.wiff	118-1	QC 30	Quality Control		☒	30.000	1.00	30.341	1.1	7.59e+004	3.10	Base To Base	☐	
40	I8-534006g\I8-0296.wiff	118-2	QC 30	Quality Control		☒	30.000	1.00	26.193	-13.	6.43e+004	3.12	Base To Base	☐	
41	I8-534006g\I8-0297.wiff	118-3	QC 30	Quality Control		☒	30.000	1.00	32.120	7.1	8.08e+004	3.13	Base To Base	☐	
42	I8-534006g\I8-0298.wiff	118-4	QC 250	Quality Control		☒	250.00	1.00	267.86	7.1	9.06e+005	3.12	Base To Base	☐	
43	I8-534006g\I8-0299.wiff	118-5	QC 250	Quality Control		☒	250.00	1.00	268.21	7.3	9.07e+005	3.14	Base To Base	☐	
44	I8-534006g\I8-0300.wiff	118-6	QC 250	Quality Control		☒	250.00	1.00	273.70	9.5	9.30e+005	3.12	Base To Base	☐	
45	I8-534006g\I8-0301.wiff	118-7	QC 750	Quality Control		☒	750.00	1.00	797.84	6.4	3.96e+006	3.10	Base To Base	☐	
46	I8-534006g\I8-0302.wiff	118-8	QC 750	Quality Control		☒	750.00	1.00	773.45	3.1	3.78e+006	3.12	Base To Base	☐	
47	I8-534006g\I8-0303.wiff	118-9	QC 750	Quality Control		☒	750.00	1.00	785.98	4.8	3.88e+006	3.10	Base To Base	☐	
48	I8-534006g\I8-0304.wiff	118-10	QC 2500	Quality Control		☒	2500.0	1.00	2148.3	-14.	1.93e+007	3.11	Base To Base	☐	
49	I8-534006g\I8-0305.wiff	118-11	QC 2500	Quality Control		☒	2500.0	1.00	2160.3	-14.	1.95e+007	3.12	Base To Base	☐	
50	I8-534006g\I8-0306.wiff	118-12	QC 2500	Quality Control		☒	2500.0	1.00	2149.1	-14.	1.93e+007	3.12	Base To Base	☐	
51	I8-534006g\I8-0307.wiff	118-13	QC 10000	Quality Control		☒	10000.	20.0	17322.	73.	4.48e+006	3.11	Base To Base	☐	
52	I8-534006g\I8-0308.wiff	118-14	QC 10000	Quality Control		☒	10000.	20.0	17622.	76.	4.59e+006	3.09	Base To Base	☐	
53	I8-534006g\I8-0309.wiff	118-15	QC 10000	Quality Control		☒	10000.	20.0	17381.	74.	4.50e+006	3.09	Base To Base	☐	

Printing Date: Thursday, March 15, 2007
Printing Time: 10:12:34 AM

Operator: Shelley Hollar
Analyst Version: 1.4.2

Results Path: \\Lcmsp03\sciexdata\Projects\534006\Bio\Results\I8-534006gr.r
Results Name: I8-534006gr.rdb



Printing Date: Thursday, March 15, 2007
Printing Time: 10:13:19 AM

Operator: Shelley Hollar
Analyst Version: 1.4.2

Table A-4: I8-534006h Data

Note:
Validation session 4

Study Record Page: 129c

Results Path: \\Lcmsp03\sciexdata\Projects\534006\Bio\Results\I8-534006hr.r
Results Name: I8-534006hr.rdb

	File Name	Sample ID	Sample Name	Sample Type	Analyte Peak Name	Use Record	Analyte Concentration (ng/mL)	Dilution Factor	Calculated Concentration (ng/mL)	%RE	Analyte Peak Area (counts)	Analyte Retention Time (min)	Analyte Integration Type	Record Modified	Sample Annotation
1	I8-534006hrI8-0310.wiff	114-1	Diluent	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
2	I8-534006hrI8-0311.wiff	124-1	Solvent Blank	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
3	I8-534006hrI8-0312.wiff	124-2	Serum Blank	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
4	I8-534006hrI8-0313.wiff	124-3	Serum Blank	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
5	I8-534006hrI8-0314.wiff	124-4	Serum Blank	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
6	I8-534006hrI8-0315.wiff	114-1	Diluent	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
7	I8-534006hrI8-0316.wiff	122-1	C 10	Standard		☒	10.000	1.00	10.221	2.2	2.66e+004	3.13	Base To Base	☐	
8	I8-534006hrI8-0317.wiff	122-2	C 10	Standard		☒	10.000	1.00	10.222	2.2	2.66e+004	3.09	Base To Base	☐	
9	I8-534006hrI8-0318.wiff	122-3	C 10	Standard		☒	10.000	1.00	9.6831	-3.2	2.49e+004	3.12	Base To Base	☐	
10	I8-534006hrI8-0319.wiff	122-4	C 30	Standard		☒	30.000	1.00	29.571	-1.4	8.81e+004	3.09	Base To Base	☐	
11	I8-534006hrI8-0320.wiff	122-5	C 30	Standard		☒	30.000	1.00	30.519	1.7	9.12e+004	3.12	Base To Base	☐	
12	I8-534006hrI8-0321.wiff	122-6	C 30	Standard		☒	30.000	1.00	28.913	-3.6	8.60e+004	3.09	Base To Base	☐	
13	I8-534006hrI8-0322.wiff	122-7	C 100	Standard		☒	100.00	1.00	98.943	-1.1	3.26e+005	3.08	Base To Base	☐	
14	I8-534006hrI8-0323.wiff	122-8	C 100	Standard		☒	100.00	1.00	98.208	-1.8	3.24e+005	3.09	Base To Base	☐	
15	I8-534006hrI8-0324.wiff	122-9	C 100	Standard		☒	100.00	1.00	99.765	-0.23	3.29e+005	3.10	Base To Base	☐	
16	I8-534006hrI8-0325.wiff	122-10	C 300	Standard		☒	300.00	1.00	302.09	0.70	1.18e+006	3.12	Base To Base	☐	
17	I8-534006hrI8-0326.wiff	122-11	C 300	Standard		☒	300.00	1.00	303.44	1.1	1.19e+006	3.09	Base To Base	☐	
18	I8-534006hrI8-0327.wiff	122-12	C 300	Standard		☒	300.00	1.00	309.26	3.1	1.22e+006	3.11	Base To Base	☐	
19	I8-534006hrI8-0328.wiff	122-13	C 1000	Standard		☒	1000.0	1.00	1001.4	0.14	5.94e+006	3.10	Base To Base	☐	
20	I8-534006hrI8-0329.wiff	122-14	C 1000	Standard		☒	1000.0	1.00	995.21	-0.48	5.88e+006	3.10	Base To Base	☐	
21	I8-534006hrI8-0330.wiff	122-15	C 1000	Standard		☒	1000.0	1.00	996.85	-0.31	5.90e+006	3.09	Base To Base	☐	
22	I8-534006hrI8-0331.wiff	122-16	C 3000	Standard		☐	3000.0	1.00	2361.2	-21.	2.32e+007	3.11	Base To Base	☐	
23	I8-534006hrI8-0332.wiff	122-17	C 3000	Standard		☐	3000.0	1.00	2388.9	-20.	2.37e+007	3.09	Base To Base	☐	
24	I8-534006hrI8-0333.wiff	122-18	C 3000	Standard		☐	3000.0	1.00	2383.0	-21.	2.36e+007	3.09	Base To Base	☐	
25	I8-534006hrI8-0334.wiff	114-1	Diluent	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
26	I8-534006hrI8-0335.wiff	123-1	QC 30	Quality Control		☒	30.000	1.00	26.686	-11.	7.88e+004	3.10	Base To Base	☐	
27	I8-534006hrI8-0336.wiff	123-2	QC 30	Quality Control		☒	30.000	1.00	27.454	-8.5	8.13e+004	3.09	Base To Base	☐	
28	I8-534006hrI8-0337.wiff	123-3	QC 30	Quality Control		☒	30.000	1.00	30.311	1.0	9.05e+004	3.12	Base To Base	☐	
29	I8-534006hrI8-0338.wiff	123-4	QC 250	Quality Control		☒	250.00	1.00	255.76	2.3	9.67e+005	3.09	Base To Base	☐	
30	I8-534006hrI8-0339.wiff	123-5	QC 250	Quality Control		☒	250.00	1.00	260.38	4.2	9.88e+005	3.10	Base To Base	☐	
31	I8-534006hrI8-0340.wiff	123-6	QC 250	Quality Control		☒	250.00	1.00	264.58	5.8	1.01e+006	3.10	Base To Base	☐	
32	I8-534006hrI8-0341.wiff	123-7	QC 750	Quality Control		☒	750.00	1.00	804.68	7.3	4.32e+006	3.11	Base To Base	☐	
33	I8-534006hrI8-0342.wiff	123-8	QC 750	Quality Control		☒	750.00	1.00	814.52	8.6	4.39e+006	3.10	Base To Base	☐	
34	I8-534006hrI8-0343.wiff	123-9	QC 750	Quality Control		☒	750.00	1.00	798.79	6.5	4.27e+006	3.11	Base To Base	☐	
35	I8-534006hrI8-0344.wiff	123-10	QC 2500	Quality Control		☒	2500.0	1.00	2199.7	-12.	2.06e+007	3.11	Base To Base	☐	
36	I8-534006hrI8-0345.wiff	123-11	QC 2500	Quality Control		☒	2500.0	1.00	2172.5	-13.	2.02e+007	3.09	Base To Base	☐	
37	I8-534006hrI8-0346.wiff	123-12	QC 2500	Quality Control		☒	2500.0	1.00	2166.0	-13.	2.01e+007	3.10	Base To Base	☐	
38	I8-534006hrI8-0347.wiff	123-13	QC 10000	Quality Control		☒	10000.	20.0	11265.	13.	2.63e+006	3.10	Base To Base	☐	
39	I8-534006hrI8-0348.wiff	123-14	QC 10000	Quality Control		☒	10000.	20.0	10601.	6.0	2.43e+006	3.09	Base To Base	☐	
40	I8-534006hrI8-0349.wiff	123-15	QC 10000	Quality Control		☒	10000.	20.0	10886.	8.9	2.51e+006	3.09	Base To Base	☐	

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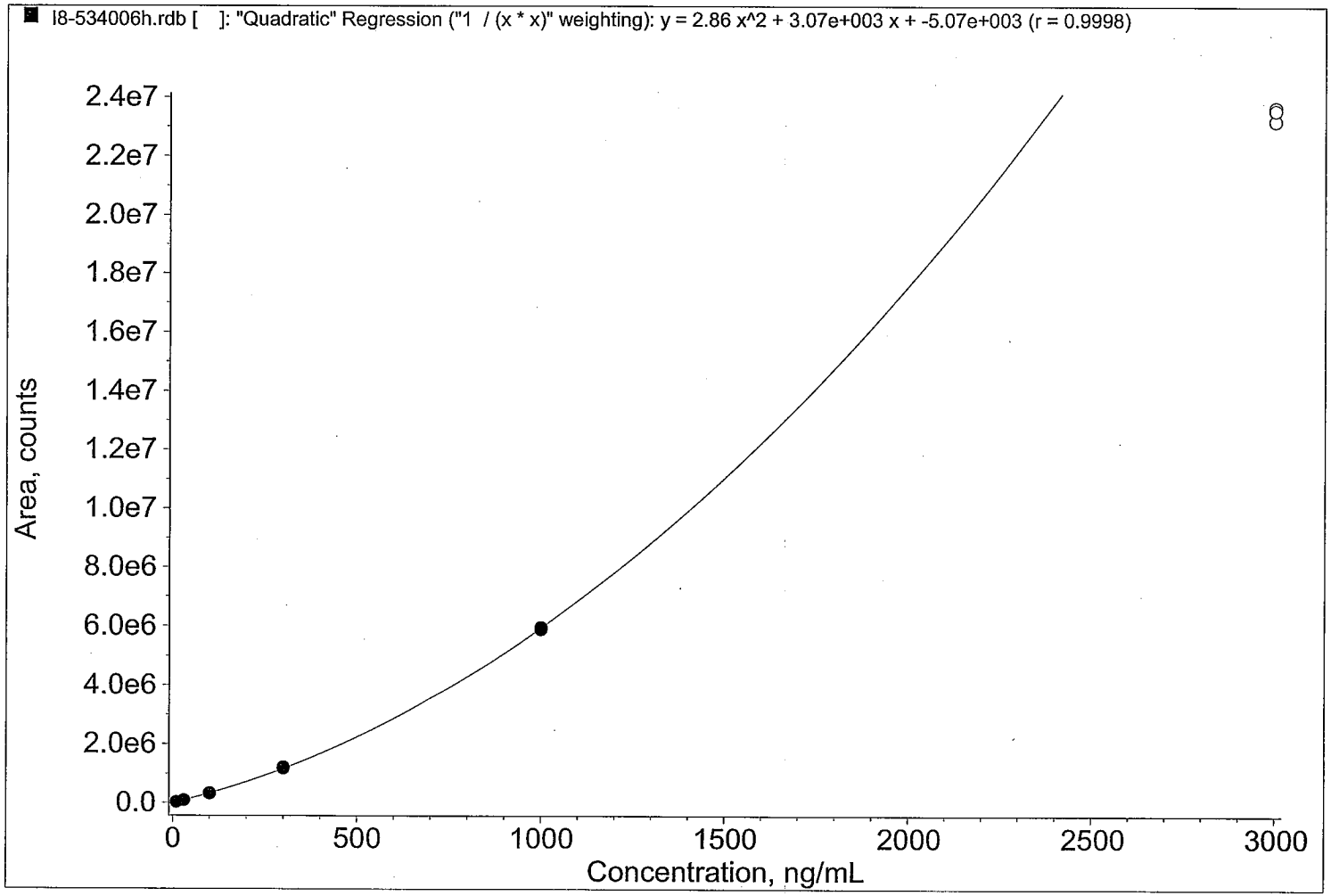
Results Path: \\Lcmsp03\sciexdata\Projects\534006\Bio\Results\I8-534006hr.r
Results Name: I8-534006hr.rdb



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Analyst Version: 1.4.2

Table A-5: I8-534006i Data

Note:
Validation session 5

Study Record Page: 129d

Results Path: \\Lcmsp03\sciexdata\Projects\534006\Bio\Results\I8-534006ir.r
Results Name: I8-534006ir.rdb

	File Name	Sample ID	Sample Name	Sample Type	Peak Name	Use Record	Analyte Concentration (ng/mL)	Dilution Factor	Calculated Concentration (ng/mL)	%RE	Analyte Peak Area (counts)	Analyte Retention Time (min)	Analyte Integration Type	Record Modified	Sample Annotation
1	I8-534006\I8-0350.wiff	114-1	Diluent	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
2	I8-534006\I8-0351.wiff	129-1	Solvent Blank	Unknown			N/A	1.00	3.3146	N/A	2.16e+003	3.17	Base To Base	☐	
3	I8-534006\I8-0352.wiff	129-2	Serum Blank	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
4	I8-534006\I8-0353.wiff	129-3	Serum Blank	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
5	I8-534006\I8-0354.wiff	129-4	Serum Blank	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
6	I8-534006\I8-0355.wiff	114-1	Diluent	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
7	I8-534006\I8-0356.wiff	127-1	C 10	Standard		☒	10.000	1.00	10.029	0.29	2.78e+004	3.09	Base To Base	☐	
8	I8-534006\I8-0357.wiff	127-2	C 10	Standard		☒	10.000	1.00	10.752	7.5	3.06e+004	3.10	Base To Base	☐	
9	I8-534006\I8-0358.wiff	127-3	C 10	Standard		☒	10.000	1.00	9.2923	-7.1	2.50e+004	3.11	Base To Base	☐	
10	I8-534006\I8-0359.wiff	127-4	C 30	Standard		☒	30.000	1.00	28.775	-4.1	1.01e+005	3.09	Base To Base	☐	
11	I8-534006\I8-0360.wiff	127-5	C 30	Standard		☒	30.000	1.00	29.126	-2.9	1.02e+005	3.08	Base To Base	☐	
12	I8-534006\I8-0361.wiff	127-6	C 30	Standard		☒	30.000	1.00	32.355	7.8	1.15e+005	3.06	Base To Base	☐	
13	I8-534006\I8-0362.wiff	127-7	C 100	Standard		☒	100.00	1.00	93.989	-6.0	3.73e+005	3.08	Base To Base	☐	
14	I8-534006\I8-0363.wiff	127-8	C 100	Standard		☒	100.00	1.00	93.837	-6.2	3.72e+005	3.11	Base To Base	☐	
15	I8-534006\I8-0364.wiff	127-9	C 100	Standard		☒	100.00	1.00	98.054	-1.9	3.91e+005	3.12	Base To Base	☐	
16	I8-534006\I8-0365.wiff	127-10	C 300	Standard		☒	300.00	1.00	320.45	6.8	1.52e+006	3.10	Base To Base	☐	
17	I8-534006\I8-0366.wiff	127-11	C 300	Standard		☒	300.00	1.00	321.67	7.2	1.53e+006	3.09	Base To Base	☐	
18	I8-534006\I8-0367.wiff	127-12	C 300	Standard		☒	300.00	1.00	294.92	-1.7	1.38e+006	3.10	Base To Base	☐	
19	I8-534006\I8-0368.wiff	127-13	C 1000	Standard		☒	1000.0	1.00	1002.6	0.26	6.94e+006	3.11	Base To Base	☐	
20	I8-534006\I8-0369.wiff	127-14	C 1000	Standard		☒	1000.0	1.00	979.31	-2.1	6.71e+006	3.09	Base To Base	☐	
21	I8-534006\I8-0370.wiff	127-15	C 1000	Standard		☒	1000.0	1.00	1002.8	0.28	6.94e+006	3.09	Base To Base	☐	
22	I8-534006\I8-0371.wiff	127-16	C 3000	Standard		☐	3000.0	1.00	2314.3	-23.	2.56e+007	3.08	Base To Base	☐	
23	I8-534006\I8-0372.wiff	127-17	C 3000	Standard		☐	3000.0	1.00	2324.3	-23.	2.58e+007	3.10	Base To Base	☐	
24	I8-534006\I8-0373.wiff	127-18	C 3000	Standard		☐	3000.0	1.00	2322.6	-23.	2.57e+007	3.08	Base To Base	☐	
25	I8-534006\I8-0374.wiff	114-1	Diluent	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
26	I8-534006\I8-0375.wiff	128-1	QC 30	Quality Control		☒	30.000	1.00	27.671	-7.8	9.66e+004	3.07	Base To Base	☐	
27	I8-534006\I8-0376.wiff	128-2	QC 30	Quality Control		☒	30.000	1.00	25.160	-16.	8.67e+004	3.10	Base To Base	☐	
28	I8-534006\I8-0377.wiff	128-3	QC 30	Quality Control		☒	30.000	1.00	28.886	-3.7	1.01e+005	3.09	Base To Base	☐	
29	I8-534006\I8-0378.wiff	128-4	QC 250	Quality Control		☒	250.00	1.00	245.08	-2.0	1.11e+006	3.10	Base To Base	☐	
30	I8-534006\I8-0379.wiff	128-5	QC 250	Quality Control		☒	250.00	1.00	246.92	-1.2	1.11e+006	3.08	Base To Base	☐	
31	I8-534006\I8-0380.wiff	128-6	QC 250	Quality Control		☒	250.00	1.00	271.40	8.6	1.25e+006	3.10	Base To Base	☐	
32	I8-534006\I8-0381.wiff	128-7	QC 750	Quality Control		☒	750.00	1.00	787.59	5.0	4.92e+006	3.10	Base To Base	☐	
33	I8-534006\I8-0382.wiff	128-8	QC 750	Quality Control		☒	750.00	1.00	806.53	7.5	5.08e+006	3.10	Base To Base	☐	
34	I8-534006\I8-0383.wiff	128-9	QC 750	Quality Control		☒	750.00	1.00	825.52	10.	5.25e+006	3.08	Base To Base	☐	
35	I8-534006\I8-0384.wiff	128-10	QC 2500	Quality Control		☒	2500.0	1.00	2187.1	-13.	2.33e+007	3.09	Base To Base	☐	
36	I8-534006\I8-0385.wiff	128-11	QC 2500	Quality Control		☒	2500.0	1.00	2164.3	-13.	2.29e+007	3.09	Base To Base	☐	
37	I8-534006\I8-0386.wiff	128-12	QC 2500	Quality Control		☒	2500.0	1.00	2087.2	-17.	2.16e+007	3.08	Base To Base	☐	
38	I8-534006\I8-0387.wiff	128-13	QC 10000	Quality Control		☒	10000.	20.0	10142.	1.4	2.72e+006	3.07	Base To Base	☐	
39	I8-534006\I8-0388.wiff	128-14	QC 10000	Quality Control		☒	10000.	20.0	10242.	2.4	2.75e+006	3.07	Base To Base	☐	
40	I8-534006\I8-0389.wiff	128-15	QC 10000	Quality Control		☒	10000.	20.0	10656.	6.6	2.90e+006	3.07	Base To Base	☐	

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Analyst Version: 1.4.2

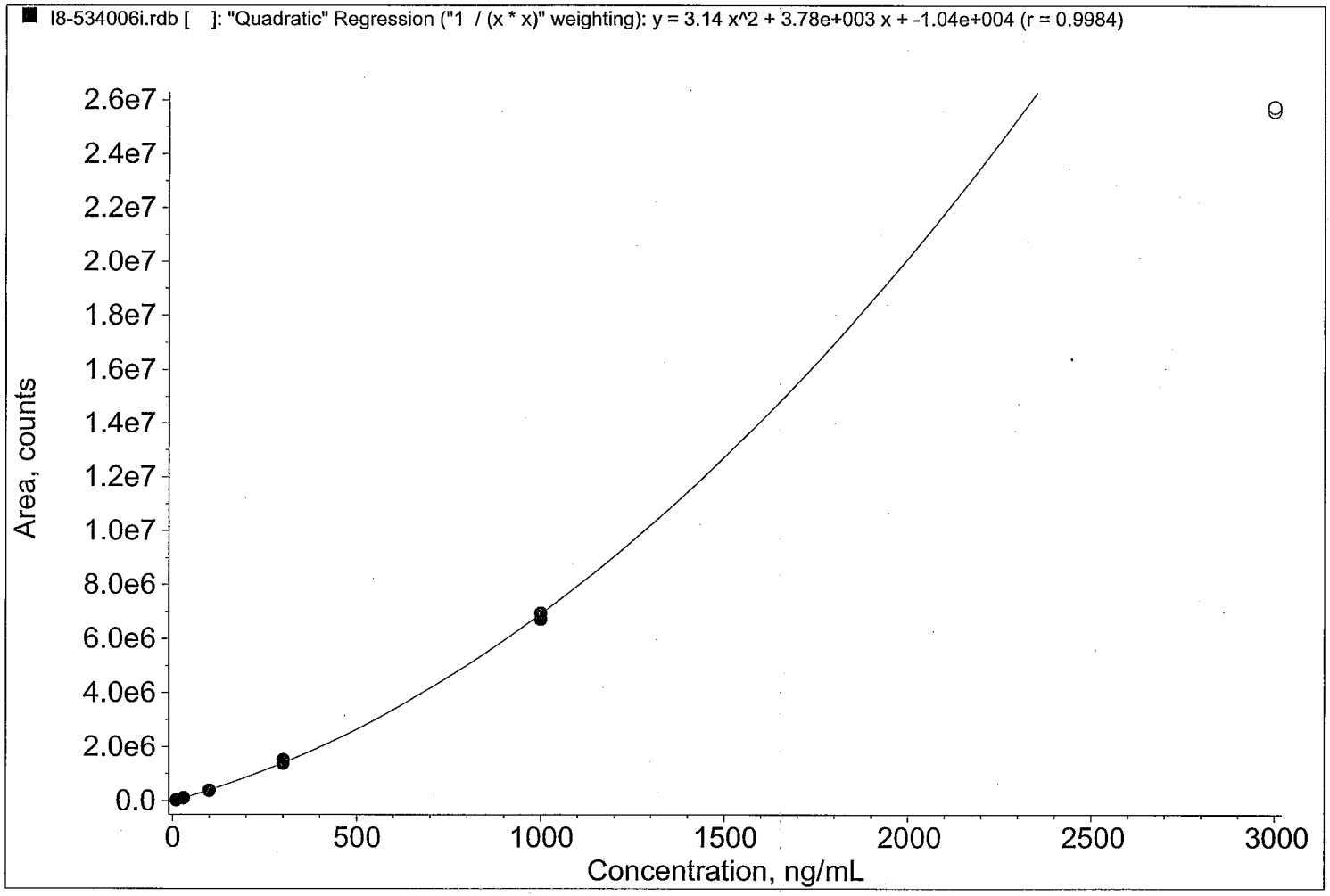
I8-534006i.rdb [ ]: "Quadratic" Regression ("1 / (x * x)" weighting): y = 3.14 x^2 + 3.78e+003 x + -1.04e+004 (r = 0.9984)
Area, counts
2.6e7
2.4e7
2.2e7
2.0e7
1.8e7
1.6e7
1.4e7
1.2e7
1.0e7
8.0e6
6.0e6
4.0e6
2.0e6
0.0
0
500
1000
1500
2000
2500
3000
Concentration, ng/mL

Table A-6: I8-534006j Data

Note:
Validation session 6

Study Record Page: 142a

Results Path: \\Lcmsp03\sciexdata\Projects\534006\Bio\Results\I8-534006jr.r
Results Name: I8-534006jr.rdb

	File Name	Sample ID	Sample Name	Sample Type	Analyte Peak Name	Use Record	Analyte Concentration (ng/mL)	Dilution Factor	Calculated Concentration (ng/mL)	%RE	Analyte Peak Area (counts)	Analyte Retention Time (min)	Analyte Integration Type	Record Modified	Sample Annotation
1	I8-534006jI8-0390.wiff	137-8	Sys Suit	Unknown	EEA		N/A	1.00	2012.9	N/A	2.64e+007	3.57	Base To Base	☐	
2	I8-534006jI8-0391.wiff	137-8	Sys Suit	Unknown	EEA		N/A	1.00	2020.4	N/A	2.66e+007	3.60	Base To Base	☐	
3	I8-534006jI8-0392.wiff	137-8	Sys Suit	Unknown	EEA		N/A	1.00	2038.0	N/A	2.70e+007	3.57	Base To Base	☐	
4	I8-534006jI8-0393.wiff	137-8	Sys Suit	Unknown	EEA		N/A	1.00	2039.5	N/A	2.70e+007	3.57	Base To Base	☐	
5	I8-534006jI8-0394.wiff	130-1	Diluent	Unknown	EEA		N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
6	I8-534006jI8-0395.wiff	135-1	Solvent Blank	Unknown	EEA		N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
7	I8-534006jI8-0396.wiff	135-2	Serum Blank	Unknown	EEA		N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
8	I8-534006jI8-0397.wiff	135-3	Serum Blank	Unknown	EEA		N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
9	I8-534006jI8-0398.wiff	135-4	Serum Blank	Unknown	EEA		N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
10	I8-534006jI8-0399.wiff	130-1	Diluent	Unknown	EEA		N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
11	I8-534006jI8-0400.wiff	133-1	C 10	Standard	EEA	☒	10.000	1.00	9.9558	-0.44	3.55e+004	3.47	Base To Base	☐	
12	I8-534006jI8-0401.wiff	133-2	C 10	Standard	EEA	☒	10.000	1.00	9.4362	-5.6	3.28e+004	3.45	Base To Base	☐	
13	I8-534006jI8-0402.wiff	133-3	C 10	Standard	EEA	☒	10.000	1.00	10.922	9.2	4.05e+004	3.44	Base To Base	☐	
14	I8-534006jI8-0403.wiff	133-4	C 30	Standard	EEA	☒	30.000	1.00	29.732	-0.89	1.40e+005	3.47	Base To Base	☐	
15	I8-534006jI8-0404.wiff	133-5	C 30	Standard	EEA	☒	30.000	1.00	28.407	-5.3	1.33e+005	3.43	Base To Base	☐	
16	I8-534006jI8-0405.wiff	133-6	C 30	Standard	EEA	☒	30.000	1.00	29.197	-2.7	1.37e+005	3.43	Base To Base	☐	
17	I8-534006jI8-0406.wiff	133-7	C 100	Standard	EEA	☒	100.00	1.00	98.731	-1.3	5.28e+005	3.43	Base To Base	☐	
18	I8-534006jI8-0407.wiff	133-8	C 100	Standard	EEA	☒	100.00	1.00	98.811	-1.2	5.29e+005	3.40	Base To Base	☐	
19	I8-534006jI8-0408.wiff	133-9	C 100	Standard	EEA	☒	100.00	1.00	97.331	-2.7	5.20e+005	3.42	Base To Base	☐	
20	I8-534006jI8-0409.wiff	133-10	C 300	Standard	EEA	☒	300.00	1.00	311.02	3.7	1.96e+006	3.40	Base To Base	☐	
21	I8-534006jI8-0410.wiff	133-11	C 300	Standard	EEA	☒	300.00	1.00	319.83	6.6	2.03e+006	3.42	Base To Base	☐	
22	I8-534006jI8-0411.wiff	133-12	C 300	Standard	EEA	☒	300.00	1.00	301.52	0.51	1.89e+006	3.41	Base To Base	☐	
23	I8-534006jI8-0412.wiff	133-13	C 1000	Standard	EEA	☒	1000.0	1.00	1002.2	0.22	9.12e+006	3.42	Base To Base	☐	
24	I8-534006jI8-0413.wiff	133-14	C 1000	Standard	EEA	☒	1000.0	1.00	998.26	-0.17	9.06e+006	3.42	Base To Base	☐	
25	I8-534006jI8-0414.wiff	133-15	C 1000	Standard	EEA	☒	1000.0	1.00	983.97	-1.6	8.88e+006	3.42	Base To Base	☐	
26	I8-534006jI8-0415.wiff	133-16	C 3000	Standard	EEA	☐	3000.0	1.00	2171.9	-28.	2.99e+007	3.41	Base To Base	☐	
27	I8-534006jI8-0416.wiff	133-17	C 3000	Standard	EEA	☐	3000.0	1.00	2130.4	-29.	2.90e+007	3.42	Base To Base	☐	
28	I8-534006jI8-0417.wiff	133-18	C 3000	Standard	EEA	☐	3000.0	1.00	2150.7	-28.	2.94e+007	3.42	Base To Base	☐	
29	I8-534006jI8-0418.wiff	130-1	Diluent	Unknown	EEA		N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
30	I8-534006jI8-0419.wiff	134-1	QC 30	Quality Control	EEA	☒	30.000	1.00	28.720	-4.3	1.34e+005	3.39	Base To Base	☐	
31	I8-534006jI8-0420.wiff	134-2	QC 30	Quality Control	EEA	☒	30.000	1.00	28.454	-5.2	1.33e+005	3.40	Base To Base	☐	
32	I8-534006jI8-0421.wiff	134-3	QC 30	Quality Control	EEA	☒	30.000	1.00	26.777	-11.	1.24e+005	3.38	Base To Base	☐	
33	I8-534006jI8-0422.wiff	134-4	QC 250	Quality Control	EEA	☒	250.00	1.00	246.29	-1.5	1.49e+006	3.40	Base To Base	☐	
34	I8-534006jI8-0423.wiff	134-5	QC 250	Quality Control	EEA	☒	250.00	1.00	245.64	-1.7	1.48e+006	3.40	Base To Base	☐	
35	I8-534006jI8-0424.wiff	134-6	QC 250	Quality Control	EEA	☒	250.00	1.00	248.88	-0.45	1.50e+006	3.37	Base To Base	☐	
36	I8-534006jI8-0425.wiff	134-7	QC 750	Quality Control	EEA	☒	750.00	1.00	806.92	7.6	6.71e+006	3.39	Base To Base	☐	
37	I8-534006jI8-0426.wiff	134-8	QC 750	Quality Control	EEA	☒	750.00	1.00	771.88	2.9	6.31e+006	3.39	Base To Base	☐	
38	I8-534006jI8-0427.wiff	134-9	QC 750	Quality Control	EEA	☒	750.00	1.00	802.28	7.0	6.65e+006	3.37	Base To Base	☐	
39	I8-534006jI8-0428.wiff	134-10	QC 2500	Quality Control	EEA	☒	2500.0	1.00	1974.4	-21.	2.56e+007	3.38	Base To Base	☐	
40	I8-534006jI8-0429.wiff	134-11	QC 2500	Quality Control	EEA	☒	2500.0	1.00	2006.0	-20.	2.63e+007	3.36	Base To Base	☐	
41	I8-534006jI8-0430.wiff	134-12	QC 2500	Quality Control	EEA	☒	2500.0	1.00	1972.7	-21.	2.56e+007	3.36	Base To Base	☐	
42	I8-534006jI8-0431.wiff	134-13	QC 10000	Quality Control	EEA	☒	10000.	20.0	12734.	27.	4.86e+006	3.38	Base To Base	☐	
43	I8-534006jI8-0432.wiff	134-14	QC 10000	Quality Control	EEA	☒	10000.	20.0	12805.	28.	4.89e+006	3.37	Base To Base	☐	
44	I8-534006jI8-0433.wiff	134-15	QC 10000	Quality Control	EEA	☒	10000.	20.0	12728.	27.	4.86e+006	3.36	Base To Base	☐	

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Operator: Shelley Hollar
Analyst Version: 1.4.2

Results Path: \\Lcmsp03\sciexdata\Projects\534006\Bio\Results\I8-534006jr.r
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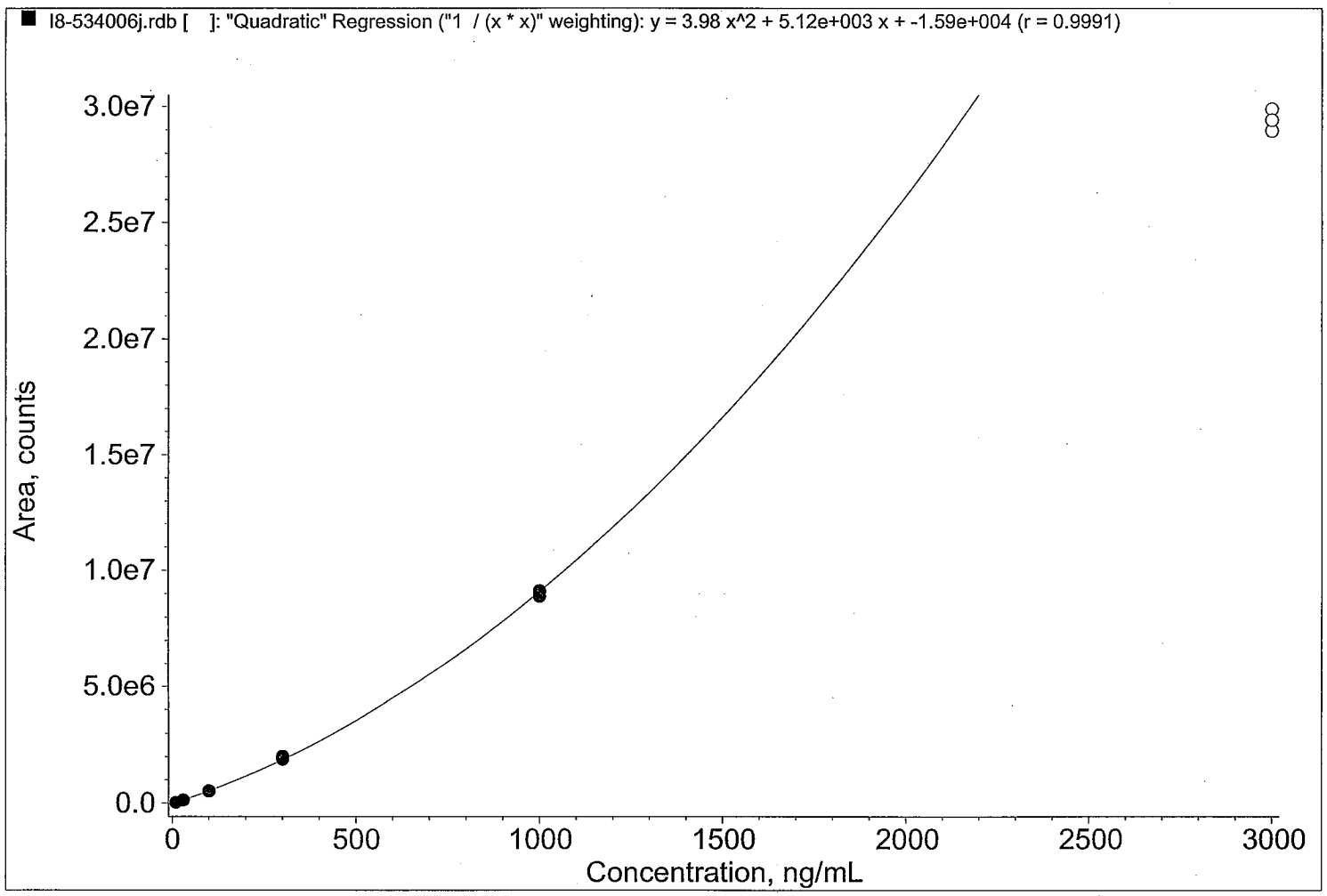

Printing Date: Thursday, March 15, 2007
Printing Time: 10:22:56 AM

Operator: Shelley Hollar
Analyst Version: 1.4.2

Table A-7: I8-534006l Data

Note:
Urine cross-validation session

Study Record Page: 150a

Results Path: \\Lcmsp03\sciexdata\Projects\534006\Bio\Results\I8-534006I.rdb
Results Name: I8-534006I.rdb

	File Name	Sample ID	Sample Name	Sample Type	Analyte Peak Name	Use Record	Analyte Concentration (ng/mL)	Dilution Factor	Calculated Concentration (ng/mL)	%RE	Analyte Peak Area (counts)	Analyte Retention Time (min)	Analyte Integration Type	Record Modified	Sample Annotation
1	I8-534006NI8-0474.wiff	145-8	Sys Suit	Unknown			N/A	1.00	1803.8	N/A	2.00e+007	3.56	Base To Base	☐	
2	I8-534006NI8-0475.wiff	145-8	Sys Suit	Unknown			N/A	1.00	2207.8	N/A	2.76e+007	3.37	Base To Base	☐	
3	I8-534006NI8-0476.wiff	145-8	Sys Suit	Unknown			N/A	1.00	2212.6	N/A	2.77e+007	3.36	Base To Base	☐	
4	I8-534006NI8-0477.wiff	145-8	Sys Suit	Unknown			N/A	1.00	2196.8	N/A	2.74e+007	3.35	Base To Base	☐	
5	I8-534006NI8-0478.wiff	143-1	Diluent	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
6	I8-534006NI8-0479.wiff	149-1	Solvent Blank	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
7	I8-534006NI8-0480.wiff	149-2	Urine Blank	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
8	I8-534006NI8-0481.wiff	149-3	Urine Blank	Unknown			N/A	1.00	2.5302	N/A	3.66e+003	3.39	Base To Base	☐	
9	I8-534006NI8-0482.wiff	149-4	Urine Blank	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
10	I8-534006NI8-0483.wiff	143-1	Diluent	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
11	I8-534006NI8-0484.wiff	147-1	C 10	Standard		☒	10.000	1.00	9.3595	-6.4	3.59e+004	3.37	Base To Base	☐	
12	I8-534006NI8-0485.wiff	147-2	C 10	Standard		☒	10.000	1.00	10.563	5.6	4.16e+004	3.38	Base To Base	☐	
13	I8-534006NI8-0486.wiff	147-3	C 10	Standard		☒	10.000	1.00	10.433	4.3	4.10e+004	3.37	Base To Base	☐	
14	I8-534006NI8-0487.wiff	147-4	C 30	Standard		☒	30.000	1.00	29.185	-2.7	1.31e+005	3.37	Base To Base	☐	
15	I8-534006NI8-0488.wiff	147-5	C 30	Standard		☒	30.000	1.00	32.801	9.3	1.49e+005	3.39	Base To Base	☐	
16	I8-534006NI8-0489.wiff	147-6	C 30	Standard		☒	30.000	1.00	25.068	-16.	1.11e+005	3.40	Base To Base	☐	
17	I8-534006NI8-0490.wiff	147-7	C 100	Standard		☒	100.00	1.00	109.61	9.6	5.47e+005	3.35	Base To Base	☐	
18	I8-534006NI8-0491.wiff	147-8	C 100	Standard		☒	100.00	1.00	83.967	-16.	4.09e+005	3.36	Base To Base	☐	
19	I8-534006NI8-0492.wiff	147-9	C 100	Standard		☒	100.00	1.00	98.997	-1.0	4.89e+005	3.37	Base To Base	☐	
20	I8-534006NI8-0493.wiff	147-10	C 300	Standard		☒	300.00	1.00	328.18	9.4	1.91e+006	3.35	Base To Base	☐	
21	I8-534006NI8-0494.wiff	147-11	C 300	Standard		☒	300.00	1.00	283.10	-5.6	1.60e+006	3.37	Base To Base	☐	
22	I8-534006NI8-0495.wiff	147-12	C 300	Standard		☒	300.00	1.00	328.25	9.4	1.91e+006	3.32	Base To Base	☐	
23	I8-534006NI8-0496.wiff	147-13	C 1000	Standard		☒	1000.0	1.00	1034.5	3.5	8.62e+006	3.29	Base To Base	☐	
24	I8-534006NI8-0497.wiff	147-14	C 1000	Standard		☒	1000.0	1.00	1017.3	1.7	8.42e+006	3.35	Base To Base	☐	
25	I8-534006NI8-0498.wiff	147-15	C 1000	Standard		☒	1000.0	1.00	927.04	-7.3	7.37e+006	3.35	Base To Base	☐	
26	I8-534006NI8-0499.wiff	143-1	Diluent	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
27	I8-534006NI8-0500.wiff	148-1	QC 30	Quality Control		☒	30.000	1.00	27.883	-7.1	1.25e+005	3.33	Base To Base	☐	
28	I8-534006NI8-0501.wiff	148-2	QC 30	Quality Control		☒	30.000	1.00	36.614	22.	1.68e+005	3.37	Base To Base	☐	
29	I8-534006NI8-0502.wiff	148-3	QC 30	Quality Control		☒	30.000	1.00	34.717	16.	1.58e+005	3.37	Base To Base	☐	
30	I8-534006NI8-0503.wiff	148-4	QC 250	Quality Control		☒	250.00	1.00	241.83	-3.3	1.33e+006	3.37	Base To Base	☐	
31	I8-534006NI8-0504.wiff	148-5	QC 250	Quality Control		☒	250.00	1.00	215.66	-14.	1.16e+006	3.37	Base To Base	☐	
32	I8-534006NI8-0505.wiff	148-6	QC 250	Quality Control		☒	250.00	1.00	242.30	-3.1	1.33e+006	3.37	Base To Base	☐	
33	I8-534006NI8-0506.wiff	148-7	QC 750	Quality Control		☒	750.00	1.00	792.88	5.7	5.93e+006	3.37	Base To Base	☐	
34	I8-534006NI8-0507.wiff	148-8	QC 750	Quality Control		☒	750.00	1.00	903.27	20.	7.11e+006	3.32	Base To Base	☐	
35	I8-534006NI8-0508.wiff	148-9	QC 750	Quality Control		☒	750.00	1.00	801.02	6.8	6.01e+006	3.34	Base To Base	☐	
36	I8-534006NI8-0509.wiff	148-10	QC 10000	Quality Control		☒	10000.	20.0	9977.8	-0.22	3.21e+006	3.36	Base To Base	☐	
37	I8-534006NI8-0510.wiff	148-11	QC 10000	Quality Control		☒	10000.	20.0	12540.	25.	4.32e+006	3.33	Base To Base	☐	
38	I8-534006NI8-0511.wiff	148-12	QC 10000	Quality Control		☒	10000.	20.0	10064.	0.64	3.24e+006	3.37	Base To Base	☐	

Printing Date: Friday, March 16, 2007
Printing Time: 7:18:27 AM

Operator: Shelley Hollar
Analyst Version: 1.4.2

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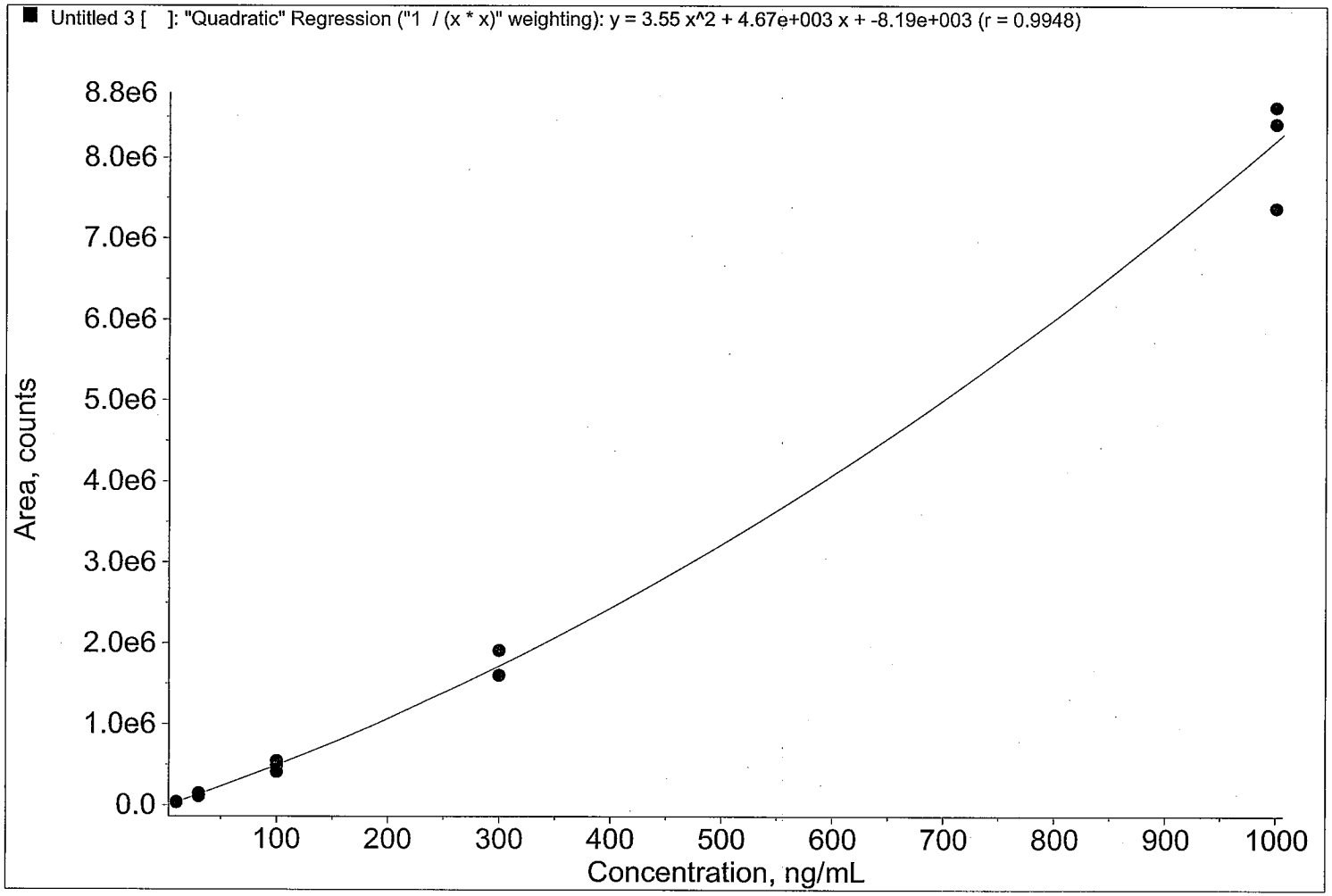

Printing Date: Friday, March 16, 2007
Printing Time: 7:19:48 AM

Operator: Shelley Hollar
Analyst Version: 1.4.2

Table A-8: I6-534006f1 Data

Note:
Experimental serum sample analysis.
Due to instrument drift only the second half of the run will be reported. The samples from the first half of the run were re-analyzed at a later date.

Study Record Page: 161d

Results Path: \\Lcmsp03\sciexdata\Projects\534006\Bio\Results\I6-534006f1revis

	File Name	Sample ID	Sample Name	Sample Type	Analyte Peak Name	Use Record	Analyte Concentration (ng/mL)	Dilution Factor	Calculated Concentration (ng/mL)	%RE	Analyte Peak Area (counts)	Analyte Retention Time (min)	Analyte Integration Type	Record Modified	Sample Annotation	LCARTRIDGETRAY	LCARTRIDGEPOSITION
1	I6-534006MI6-0617.wiff	152-8	Test Solution	Unknown			N/A	1.00	1147.2	N/A	3.89e+007	5.95	Base To Base	☐		10	A1
2	I6-534006MI6-0618.wiff	152-8	Test Solution	Unknown			N/A	1.00	980.17	N/A	3.69e+007	5.99	Base To Base	☐		10	B1
3	I6-534006MI6-0619.wiff	152-8	Test Solution	Unknown			N/A	1.00	1275.4	N/A	3.95e+007	6.01	Base To Base	☐		10	C1
4	I6-534006MI6-0620.wiff	152-8	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	3.96e+007	5.91	Base To Base	☐		10	C1
5	I6-534006MI6-0621.wiff	152-8	Test Solution	Unknown			N/A	1.00	1168.1	N/A	3.90e+007	5.95	Valley	☐		10	C1
6	I6-534006MI6-0622.wiff	152-8	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	4.03e+007	5.98	Base To Base	☐		10	A1
7	I6-534006MI6-0623.wiff	152-8	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	4.09e+007	6.00	Base To Base	☐		10	B1
8	I6-534006MI6-0624.wiff	152-8	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	4.10e+007	5.93	Base To Base	☐		10	C1
9	I6-534006MI6-0625.wiff	152-8	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	4.13e+007	5.96	Base To Base	☐		10	C1
10	I6-534006MI6-0626.wiff	152-8	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	4.18e+007	5.95	Base To Base	☐		10	C1
11	I6-534006MI6-0627.wiff	151-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	D1
12	I6-534006MI6-0628.wiff	156-1	Solvent Blank	Unknown			N/A	1.00	0.27302	N/A	6.09e+004	5.88	Base To Base	☐		10	E1
13	I6-534006MI6-0629.wiff	156-2	Blank Serum	Unknown			N/A	1.00	0.77502	N/A	9.09e+004	6.01	Base To Base	☐		10	F1
14	I6-534006MI6-0630.wiff	156-3	Blank Serum	Unknown			N/A	1.00	1.0286	N/A	1.06e+005	5.97	Base To Base	☐		10	G1
15	I6-534006MI6-0631.wiff	156-4	Blank Serum	Unknown			N/A	1.00	1.0162	N/A	1.05e+005	5.94	Base To Base	☐		10	H1
16	I6-534006MI6-0632.wiff	151-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	G2
17	I6-534006MI6-0633.wiff	154-1	C 10	Standard		☐	10.000	1.00	9.0798	-9.2	5.85e+005	5.94	Base To Base	☐		10	C3
18	I6-534006MI6-0634.wiff	154-4	C 30	Standard		☐	30.000	1.00	23.682	-21.	1.45e+006	5.87	Base To Base	☐		10	F3
19	I6-534006MI6-0635.wiff	154-7	C 100	Standard		☐	100.00	1.00	85.103	-15.	4.96e+006	5.83	Base To Base	☐		10	H3
20	I6-534006MI6-0636.wiff	154-10	C 300	Standard		☐	300.00	1.00	242.09	-19.	1.32e+007	5.84	Base To Base	☐		10	C4
21	I6-534006MI6-0637.wiff	154-13	C 1000	Standard		☐	1000.0	1.00	793.60	-21.	3.32e+007	5.77	Base To Base	☐		10	F4
22	I6-534006MI6-0638.wiff	151-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	C6
23	I6-534006MI6-0639.wiff	155-1	QC 30	Quality Control		☒	30.000	1.00	25.040	-17.	1.53e+006	5.75	Base To Base	☒		10	E6
24	I6-534006MI6-0640.wiff	155-4	QC 250	Quality Control		☒	250.00	1.00	178.95	-28.	1.00e+007	5.72	Base To Base	☐		10	G6
25	I6-534006MI6-0641.wiff	155-7	QC 750	Quality Control		☒	750.00	1.00	571.40	-24.	2.68e+007	5.73	Valley	☐		10	D7
26	I6-534006MI6-0642.wiff	155-10	QC 10000	Quality Control		☒	10000.	20.0	7066.2	-29.	1.83e+007	5.70	Base To Base	☐		10	A7
27	I6-534006MI6-0643.wiff	151-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	D1
28	I6-534006MI6-0644.wiff	157-1	46662,D0,1M,T0	Unknown			N/A	1.00	2.5888	N/A	1.99e+005	5.61	Base To Base	☐		10	D1
29	I6-534006MI6-0645.wiff	157-2	46663,D0,1M,T0	Unknown			N/A	1.00	1.5896	N/A	1.39e+005	5.59	Base To Base	☐		10	D1
30	I6-534006MI6-0646.wiff	157-3	46665,D0,1M,T0	Unknown			N/A	1.00	1.7773	N/A	1.51e+005	5.67	Base To Base	☐		10	D1
31	I6-534006MI6-0647.wiff	157-4	46678,D0,1F,T0	Unknown			N/A	1.00	1.3670	N/A	1.26e+005	5.57	Base To Base	☐		10	D1
32	I6-534006MI6-0648.wiff	157-5	46679,D0,1F,T0	Unknown			N/A	1.00	4.7954	N/A	3.30e+005	5.55	Base To Base	☐		10	D1
33	I6-534006MI6-0649.wiff	157-6	46680,D0,1F,T0	Unknown			N/A	1.00	1.3934	N/A	1.28e+005	5.55	Base To Base	☐		10	D1
34	I6-534006MI6-0650.wiff	157-7	46666,D0,1M,T2 min	Unknown			N/A	1.00	No Intercept	#BAD!	4.86e+008	5.42	Base To Base	☐		10	D1
35	I6-534006MI6-0651.wiff	157-8	46669,D0,1M,T2 min	Unknown			N/A	1.00	No Intercept	#BAD!	2.47e+008	5.49	Base To Base	☐		10	D1
36	I6-534006MI6-0652.wiff	157-9	46672,D0,1M,T2 min	Unknown			N/A	1.00	No Intercept	#BAD!	5.27e+008	5.41	Base To Base	☐		10	D1
37	I6-534006MI6-0653.wiff	157-10	46681,D0,1F,T2 min	Unknown			N/A	1.00	No Intercept	#BAD!	5.44e+008	5.47	Base To Base	☐		10	D1
38	I6-534006MI6-0654.wiff	157-11	46684,D0,1F,T2 min	Unknown			N/A	1.00	No Intercept	#BAD!	5.19e+008	5.54	Base To Base	☐		10	D1
39	I6-534006MI6-0655.wiff	157-12	46685,D0,1F,T2 min	Unknown			N/A	1.00	No Intercept	#BAD!	5.04e+008	5.42	Base To Base	☐		10	D1
40	I6-534006MI6-0656.wiff	157-13	46673,D0,1M,T10min	Unknown			N/A	1.00	No Intercept	#BAD!	4.72e+008	5.42	Base To Base	☐		10	D1
41	I6-534006MI6-0657.wiff	157-14	46674,D0,1M,T10min	Unknown			N/A	1.00	No Intercept	#BAD!	4.56e+008	5.39	Base To Base	☐		10	D1
42	I6-534006MI6-0658.wiff	157-15	46676,D0,1M,T10min	Unknown			N/A	1.00	No Intercept	#BAD!	4.83e+008	5.42	Valley	☐		10	D1
43	I6-534006MI6-0659.wiff	157-16	46686,D0,1F,T10min	Unknown			N/A	1.00	No Intercept	#BAD!	4.33e+008	5.46	Base To Base	☐		10	D1
44	I6-534006MI6-0660.wiff	157-17	46688,D0,1F,T10min	Unknown			N/A	1.00	No Intercept	#BAD!	3.96e+008	5.42	Base To Base	☐		10	D1
45	I6-534006MI6-0661.wiff	157-18	46691,D0,1F,T10min	Unknown			N/A	1.00	No Intercept	#BAD!	4.36e+008	5.36	Base To Base	☐		10	D1
46	I6-534006MI6-0662.wiff	157-19	46662,D0,1M,T20 min	Unknown			N/A	1.00	No Intercept	#BAD!	4.61e+008	5.35	Base To Base	☐		10	D1
47	I6-534006MI6-0663.wiff	157-20	46663,D0,1M,T20 min	Unknown			N/A	1.00	No Intercept	#BAD!	4.27e+008	5.34	Base To Base	☐		10	D1
48	I6-534006MI6-0664.wiff	157-21	46665,D0,1M,T20 min	Unknown			N/A	1.00	No Intercept	#BAD!	4.55e+008	5.37	Valley	☐		10	D1
49	I6-534006MI6-0665.wiff	157-22	46678,D0,1F,T20 min	Unknown			N/A	1.00	No Intercept	#BAD!	3.50e+008	5.42	Base To Base	☐		10	D1
50	I6-534006MI6-0666.wiff	157-23	46679,D0,1F,T20 min	Unknown			N/A	1.00	No Intercept	#BAD!	3.31e+008	5.43	Base To Base	☐		10	D1
51	I6-534006MI6-0667.wiff	157-24	46680,D0,1F,T20 min	Unknown			N/A	1.00	No Intercept	#BAD!	3.44e+008	5.44	Base To Base	☐		10	D1
52	I6-534006MI6-0668.wiff	158-1	46666,D0,1M,T30 min	Unknown			N/A	1.00	No Intercept	#BAD!	4.33e+008	5.36	Base To Base	☐		10	D1
53	I6-534006MI6-0669.wiff	158-2	46669,D0,1M,T30 min	Unknown			N/A	1.00	No Intercept	#BAD!	3.07e+008	5.44	Base To Base	☐		10	D1
54	I6-534006MI6-0670.wiff	158-3	46672,D0,1M,T30 min	Unknown			N/A	1.00	No Intercept	#BAD!	4.51e+008	5.46	Base To Base	☐		10	D1
55	I6-534006MI6-0671.wiff	158-4	46681,D0,1F,T30 min	Unknown			N/A	1.00	No Intercept	#BAD!	3.42e+008	5.44	Base To Base	☐		10	D1
56	I6-534006MI6-0672.wiff	158-5	46684,D0,1F,T30 min	Unknown			N/A	1.00	No Intercept	#BAD!	3.18e+008	5.44	Base To Base	☐		10	D1
57	I6-534006MI6-0673.wiff	158-6	46685,D0,1F,T30 min	Unknown			N/A	1.00	No Intercept	#BAD!	3.03e+008	5.42	Base To Base	☐		10	D1
58	I6-534006MI6-0674.wiff	158-7	46673,D0,1M,T1 hr	Unknown			N/A	1.00	No Intercept	#BAD!	4.52e+008	5.45	Base To Base	☐		10	D1
59	I6-534006MI6-0675.wiff	158-8	46674,D0,1M,T1 hr	Unknown			N/A	1.00	No Intercept	#BAD!	4.07e+008	5.37	Base To Base	☐		10	D1
60	I6-534006MI6-0676.wiff	158-9	46676,D0,1M,T1 hr	Unknown			N/A	1.00	No Intercept	#BAD!	4.54e+008	5.41	Base To Base	☐		10	D1
61	I6-534006MI6-0677.wiff	151-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	D1
62	I6-534006MI6-0678.wiff	154-2	C 10	Standard		☒	10.000	1.00	10.020	0.20	6.41e+005	5.46	Base To Base	☐		10	E3
63	I6-534006MI6-0679.wiff	154-5	C 30	Standard		☒	30.000	1.00	29.753	-0.82	1.86e+006	5.44	Base To Base	☐		10	F3
64	I6-534006MI6-0680.wiff	154-8	C 100	Standard		☒	100.00	1.00	107.20	7.2	6.19e+006	5.50	Base To Base	☐		10	B4
65	I6-534006MI6-0681.wiff	154-11	C 300	Standard		☒	300.00	1.00	288.20	-3.9	1.54e+007	5.45	Base To Base	☐		10	E4
66	I6-534006MI6-0682.wiff	154-14	C 1000	Standard		☒	1000.0	1.00	1103.4	10.	3.85e+007	5.41	Base To Base	☐		10	G4

Printing Date: Monday, March 26, 2007

Operator: Shelley Hollar

	File Name	Sample ID	Sample Name	Sample Type	Analyte Peak Name	Use Record	Analyte Concentration (ng/mL)	Dilution Factor	Calculated Concentration (ng/mL)	%RE	Analyte Peak Area (counts)	Analyte Retention Time (min)	Analyte Integration Type	Record Modified	Sample Annotation	LCARTRIDGETRAY	LCARTRIDGEPOSITION
67	I6-534006MI6-0683.wiff	151-1	Mobile Phase	Unknown		☐	N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	C6
68	I6-534006MI6-0684.wiff	155-2	QC 30	Quality Control		☒	30.000	1.00	28.021	-6.6	1.70e+006	5.42	Base To Base	☐		10	E6
69	I6-534006MI6-0685.wiff	155-5	QC 250	Quality Control		☒	250.00	1.00	216.53	-13.	1.19e+007	5.39	Base To Base	☐		10	G6
70	I6-534006MI6-0686.wiff	155-8	QC 750	Quality Control		☒	750.00	1.00	822.58	9.7	3.39e+007	5.36	Base To Base	☐		10	D7
71	I6-534006MI6-0687.wiff	155-11	QC 10000	Quality Control		☒	10000.	20.0	9570.4	-4.3	2.35e+007	5.37	Base To Base	☐		10	A7
72	I6-534006MI6-0688.wiff	151-1	Mobile Phase	Unknown		☐	N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	D1
73	I6-534006MI6-0689.wiff	158-10	46686,D0,1F,T1 hr	Unknown		☐	N/A	1.00	No Intercept	#BAD!	1.45e+008	5.33	Valley	☐		10	D1
74	I6-534006MI6-0690.wiff	158-11	46688,D0,1F,T1 hr	Unknown		☐	N/A	1.00	No Intercept	#BAD!	1.97e+008	5.37	Valley	☐		10	D1
75	I6-534006MI6-0691.wiff	158-12	46691,D0,1F,T1 hr	Unknown		☐	N/A	1.00	No Intercept	#BAD!	2.80e+008	5.30	Base To Base	☐		10	D1
76	I6-534006MI6-0692.wiff	158-13	46662,D0,1M,T3 hr	Unknown		☐	N/A	1.00	No Intercept	#BAD!	3.82e+008	5.24	Base To Base	☐		10	D1
77	I6-534006MI6-0693.wiff	158-14	46663,D0,1M,T3 hr	Unknown		☐	N/A	1.00	No Intercept	#BAD!	2.65e+008	5.23	Base To Base	☐		10	D1
78	I6-534006MI6-0694.wiff	158-15	46665,D0,1M,T3 hr	Unknown		☐	N/A	1.00	No Intercept	#BAD!	3.11e+008	5.21	Base To Base	☐		10	D1
79	I6-534006MI6-0695.wiff	158-16	46678,D0,1F,T3 hr	Unknown		☐	N/A	1.00	No Intercept	#BAD!	4.85e+007	5.33	Base To Base	☐		10	D1
80	I6-534006MI6-0696.wiff	158-17	46679,D0,1F,T3 hr	Unknown		☐	N/A	1.00	992.08	N/A	3.71e+007	5.32	Base To Base	☐		10	D1
81	I6-534006MI6-0697.wiff	158-18	46680,D0,1F,T3 hr	Unknown		☐	N/A	1.00	625.06	N/A	2.86e+007	5.31	Valley	☐		10	D1
82	I6-534006MI6-0698.wiff	158-19	46666,D0,1M,T5 hr	Unknown		☐	N/A	1.00	No Intercept	#BAD!	1.92e+008	5.30	Base To Base	☐		10	D1
83	I6-534006MI6-0699.wiff	158-20	46669,D0,1M,T5 hr	Unknown		☐	N/A	1.00	No Intercept	#BAD!	2.94e+008	5.23	Valley	☐		10	D1
84	I6-534006MI6-0700.wiff	158-21	46672,D0,1M,T5 hr	Unknown		☐	N/A	1.00	No Intercept	#BAD!	2.78e+008	5.21	Base To Base	☐		10	D1
85	I6-534006MI6-0701.wiff	158-22	46681,D0,1F,T5 hr	Unknown		☐	N/A	1.00	638.80	N/A	2.90e+007	5.24	Base To Base	☐		10	D1
86	I6-534006MI6-0702.wiff	158-23	46684,D0,1F,T5 hr	Unknown		☐	N/A	1.00	285.27	N/A	1.52e+007	5.27	Base To Base	☐		10	D1
87	I6-534006MI6-0703.wiff	158-24	46685,D0,1F,T5 hr	Unknown		☐	N/A	1.00	159.98	N/A	9.02e+006	5.26	Base To Base	☐		10	D1
88	I6-534006MI6-0704.wiff	159-1	46673,D0,1M,T7 hr	Unknown		☐	N/A	1.00	No Intercept	#BAD!	3.28e+008	5.21	Base To Base	☐		10	D1
89	I6-534006MI6-0705.wiff	159-2	46674,D0,1M,T7 hr	Unknown		☐	N/A	1.00	No Intercept	#BAD!	1.80e+008	5.26	Base To Base	☐		10	D1
90	I6-534006MI6-0706.wiff	159-3	46676,D0,1M,T7 hr	Unknown		☐	N/A	1.00	No Intercept	#BAD!	2.96e+008	5.25	Base To Base	☐		10	D1
91	I6-534006MI6-0707.wiff	159-4	46686,D0,1F,T7 hr	Unknown		☐	N/A	1.00	408.50	N/A	2.07e+007	5.29	Base To Base	☐		10	D1
92	I6-534006MI6-0708.wiff	159-5	46688,D0,1F,T7 hr	Unknown		☐	N/A	1.00	77.046	N/A	4.51e+006	5.25	Base To Base	☐		10	D1
93	I6-534006MI6-0709.wiff	159-6	46691,D0,1F,T7 hr	Unknown		☐	N/A	1.67	175.80	N/A	6.09e+006	5.29	Base To Base	☐		10	D1
94	I6-534006MI6-0710.wiff	159-7	46662,D0,1M,T24 hr	Unknown		☐	N/A	1.00	395.41	N/A	2.01e+007	5.27	Base To Base	☐		10	D1
95	I6-534006MI6-0711.wiff	159-8	46663,D0,1M,T24 hr	Unknown		☐	N/A	1.00	73.163	N/A	4.29e+006	5.31	Base To Base	☐		10	D1
96	I6-534006MI6-0712.wiff	159-9	46665,D0,1M,T24 hr	Unknown		☐	N/A	1.00	106.01	N/A	6.12e+006	5.32	Base To Base	☐		10	D1
97	I6-534006MI6-0713.wiff	159-10	46678,D0,1F,T24 hr	Unknown		☐	N/A	1.00	13.162	N/A	8.27e+005	5.31	Base To Base	☐		10	D1
98	I6-534006MI6-0714.wiff	159-11	46679,D0,1F,T24 hr	Unknown		☐	N/A	1.00	9.9031	N/A	6.34e+005	5.32	Base To Base	☐		10	D1
99	I6-534006MI6-0715.wiff	159-12	46680,D0,1F,T24 hr	Unknown		☐	N/A	1.00	12.459	N/A	7.85e+005	5.35	Base To Base	☐		10	D1
100	I6-534006MI6-0716.wiff	159-13	46666,D0,1M,T48 hr	Unknown		☐	N/A	1.00	18.261	N/A	1.13e+006	5.34	Base To Base	☐		10	D1
101	I6-534006MI6-0717.wiff	159-14	46669,D0,1M,T48 hr	Unknown		☐	N/A	1.00	178.01	N/A	9.96e+006	5.37	Base To Base	☐		10	D1
102	I6-534006MI6-0718.wiff	159-15	46672,D0,1M,T48 hr	Unknown		☐	N/A	1.00	22.969	N/A	1.40e+006	5.30	Base To Base	☐		10	D1
103	I6-534006MI6-0719.wiff	159-16	46681,D0,1F,T48 hr	Unknown		☐	N/A	1.00	13.444	N/A	8.43e+005	5.36	Base To Base	☐		10	D1
104	I6-534006MI6-0720.wiff	159-17	46684,D0,1F,T48 hr	Unknown		☐	N/A	1.00	7.0183	N/A	4.63e+005	5.32	Base To Base	☐		10	D1
105	I6-534006MI6-0721.wiff	159-18	46685,D0,1F,T48 hr	Unknown		☐	N/A	1.00	13.505	N/A	8.47e+005	5.54	Base To Base	☐		10	D1
106	I6-534006MI6-0722.wiff	151-1	Mobile Phase	Unknown		☐	N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	C6
107	I6-534006MI6-0723.wiff	155-3	QC 30	Quality Control		☒	30.000	1.00	27.373	-8.8	1.66e+006	5.32	Base To Base	☒		10	E6
108	I6-534006MI6-0724.wiff	155-6	QC 250	Quality Control		☒	250.00	1.00	225.29	-9.9	1.24e+007	5.31	Base To Base	☐		10	G6
109	I6-534006MI6-0725.wiff	155-9	QC 750	Quality Control		☒	750.00	1.00	789.27	5.2	3.31e+007	5.25	Base To Base	☐		10	D7
110	I6-534006MI6-0726.wiff	155-12	QC 10000	Quality Control		☒	10000.	20.0	8752.6	-12.	2.19e+007	5.25	Base To Base	☐		10	A7
111	I6-534006MI6-0727.wiff	151-1	Mobile Phase	Unknown		☐	N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	D1
112	I6-534006MI6-0728.wiff	154-3	C 10	Standard		☒	10.000	1.00	9.8150	-1.9	6.28e+005	5.28	Base To Base	☐		10	E3
113	I6-534006MI6-0729.wiff	154-6	C 30	Standard		☒	30.000	1.00	31.230	4.1	1.89e+006	5.32	Base To Base	☐		10	F3
114	I6-534006MI6-0730.wiff	154-9	C 100	Standard		☒	100.00	1.00	104.26	4.3	6.02e+006	5.27	Base To Base	☐		10	B4
115	I6-534006MI6-0731.wiff	154-12	C 300	Standard		☒	300.00	1.00	252.08	-16.	1.37e+007	5.26	Base To Base	☐		10	E4
116	I6-534006MI6-0732.wiff	154-15	C 1000	Standard		☒	1000.0	1.00	1065.5	6.6	3.81e+007	5.22	Base To Base	☐		10	G4

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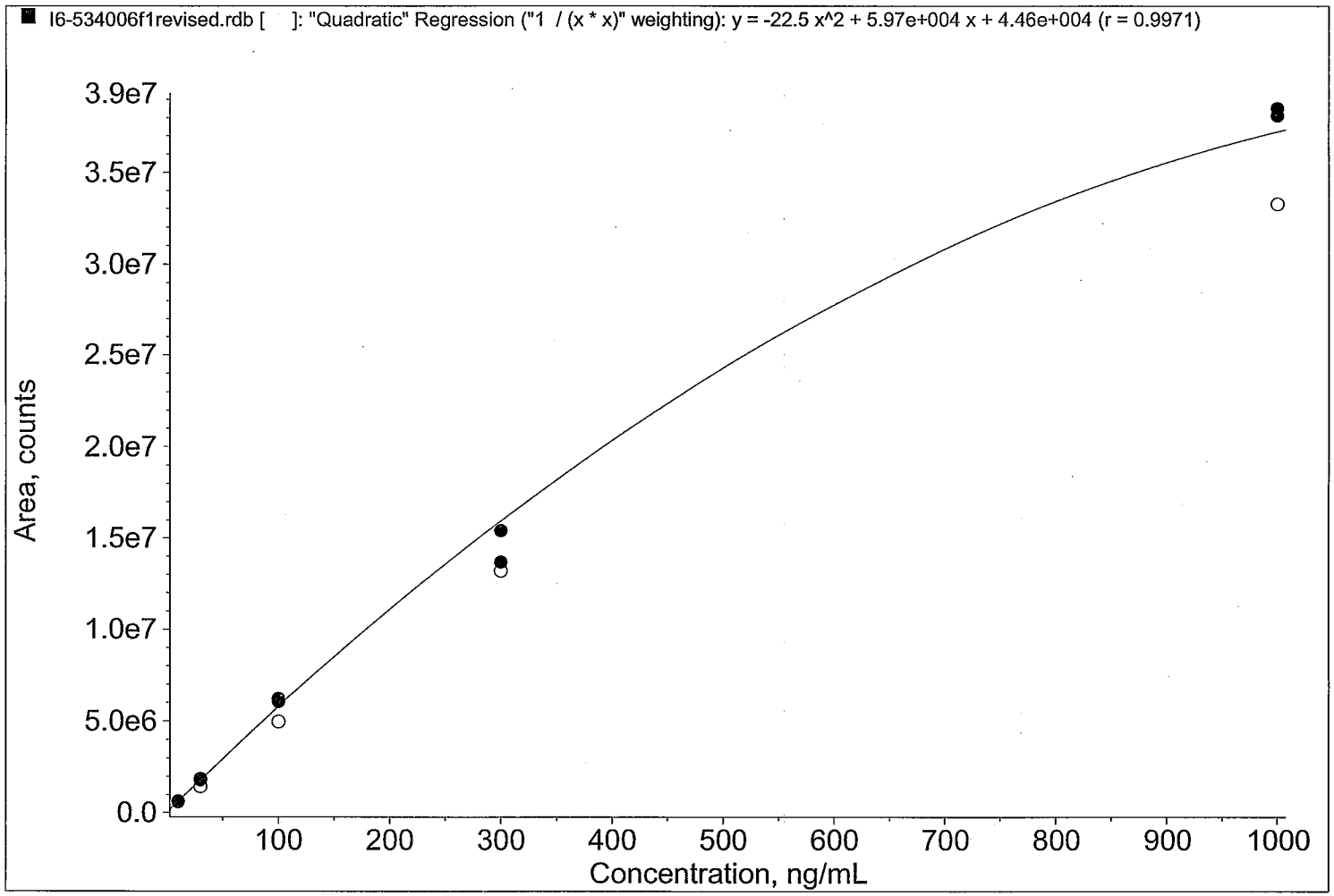
Results Name: I6-534006f1revised.rdb



Printing Date: Thursday, March 29, 2007
Printing Time: 6:22:16 PM

Operator: Shelley Hollar
Analyst Version: 1.4.2

Table A-9: I6-534006g Data

Note:
0-6 hour, 6-12 hour and 12-24 hour experimental urine and cage wash samples

Study Record Page: 173a

	File Name	Sample ID	Sample Name	Sample Type	Analyte Peak Name	Use Record	Analyte Concentration (ng/mL)	Dilution Factor	Calculated Concentration (ng/mL)	%RE	Analyte Peak Area (counts)	Analyte Retention Time (min)	Analyte Integration Type	Record Modified	Sample Annotation	LCARTRIDGETRAY	LCARTRIDGEPOSITION
1	l6-534006g\l6-0733.wiff	162-8	Test Solution	Unknown			N/A	1.00	2274.3	N/A	2.93e+007	5.34	Base To Base	☐		10	A1
2	l6-534006g\l6-0734.wiff	162-8	Test Solution	Unknown			N/A	1.00	2199.2	N/A	2.85e+007	5.32	Base To Base	☐		10	B1
3	l6-534006g\l6-0735.wiff	162-8	Test Solution	Unknown			N/A	1.00	2234.6	N/A	2.88e+007	5.34	Base To Base	☐		10	C1
4	l6-534006g\l6-0736.wiff	162-8	Test Solution	Unknown			N/A	1.00	2251.0	N/A	2.90e+007	5.29	Base To Base	☐		10	C1
5	l6-534006g\l6-0737.wiff	162-8	Test Solution	Unknown			N/A	1.00	2210.9	N/A	2.86e+007	5.37	Valley	☐		10	C1
6	l6-534006g\l6-0738.wiff	162-8	Test Solution	Unknown			N/A	1.00	2169.0	N/A	2.82e+007	5.27	Base To Base	☐		10	A1
7	l6-534006g\l6-0739.wiff	168a-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	D1
8	l6-534006g\l6-0740.wiff	166-1	Solvent Blank	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	E1
9	l6-534006g\l6-0741.wiff	166-2	Blank Urine	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	F1
10	l6-534006g\l6-0742.wiff	166-3	Blank Urine	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	G1
11	l6-534006g\l6-0743.wiff	166-4	Blank Urine	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	H1
12	l6-534006g\l6-0744.wiff	168a-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	G2
13	l6-534006g\l6-0745.wiff	164-1	C 10	Standard		☒	10.000	1.00	11.648	16.	2.56e+005	5.43	Base To Base	☐		10	C3
14	l6-534006g\l6-0746.wiff	164-4	C 30	Standard		☒	30.000	1.00	27.360	-8.8	4.96e+005	5.54	Base To Base	☐		10	F3
15	l6-534006g\l6-0747.wiff	164-7	C 100	Standard		☒	100.00	1.00	104.42	4.4	1.66e+006	5.35	Base To Base	☐		10	H3
16	l6-534006g\l6-0748.wiff	164-10	C 300	Standard		☒	300.00	1.00	314.61	4.9	4.79e+006	5.44	Base To Base	☐		10	C4
17	l6-534006g\l6-0749.wiff	164-13	C 1000	Standard		☒	1000.0	1.00	974.28	-2.6	1.40e+007	5.43	Base To Base	☐		10	F4
18	l6-534006g\l6-0750.wiff	168a-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	C6
19	l6-534006g\l6-0751.wiff	165-1	QC 30	Quality Control		☒	30.000	1.00	27.402	-8.7	4.97e+005	5.48	Base To Base	☐		10	E6
20	l6-534006g\l6-0752.wiff	165-4	QC 250	Quality Control		☒	250.00	1.00	232.58	-7.0	3.58e+006	5.47	Base To Base	☐		10	G6
21	l6-534006g\l6-0753.wiff	165-7	QC 750	Quality Control		☒	750.00	1.00	696.98	-7.1	1.02e+007	5.49	Base To Base	☐		10	D7
22	l6-534006g\l6-0754.wiff	165-10	QC 10000	Quality Control		☒	10000.	20.0	9515.5	-4.8	7.11e+006	5.51	Base To Base	☐		10	A7
23	l6-534006g\l6-0755.wiff	168a-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	D1
24	l6-534006g\l6-0756.wiff	167-1	46664, 0-6 hr	Unknown			N/A	1.00	No Intercept	#BAD!	5.61e+008	5.41	Base To Base	☐		10	D1
25	l6-534006g\l6-0757.wiff	167-2	46664, 0-6 hr rinse	Unknown			N/A	1.00	No Intercept	#BAD!	1.24e+008	5.44	Base To Base	☐		10	D1
26	l6-534006g\l6-0758.wiff	167-3	46667, 0-6 hr rinse	Unknown			N/A	1.00	No Intercept	#BAD!	3.94e+008	5.35	Base To Base	☐		10	D1
27	l6-534006g\l6-0759.wiff	167-4	46670, 0-6 hr	Unknown			N/A	1.00	No Intercept	#BAD!	5.72e+008	5.52	Valley	☐		10	D1
28	l6-534006g\l6-0760.wiff	167-5	46670, 0-6 hr rinse	Unknown			N/A	1.00	No Intercept	#BAD!	7.23e+007	5.40	Base To Base	☐		10	D1
29	l6-534006g\l6-0761.wiff	167-6	46682, 0-6 hr	Unknown			N/A	1.00	No Intercept	#BAD!	3.68e+008	5.70	Valley	☐		10	D1
30	l6-534006g\l6-0762.wiff	167-7	46682, 0-6 hr rinse	Unknown			N/A	1.00	3948.8	N/A	4.36e+007	5.46	Base To Base	☐		10	D1
31	l6-534006g\l6-0763.wiff	167-8	46683, 0-6 hr	Unknown			N/A	1.00	No Intercept	#BAD!	5.02e+008	5.65	Base To Base	☐		10	D1
32	l6-534006g\l6-0764.wiff	167-9	46683, 0-6 hr rinse	Unknown			N/A	1.00	No Intercept	#BAD!	1.55e+008	5.36	Valley	☐		10	D1
33	l6-534006g\l6-0765.wiff	167-10	46690, 0-6 hr	Unknown			N/A	1.00	No Intercept	#BAD!	5.08e+008	5.47	Valley	☐		10	D1
34	l6-534006g\l6-0766.wiff	167-11	46690, 0-6 hr rinse	Unknown			N/A	1.00	No Intercept	#BAD!	9.65e+007	5.40	Base To Base	☐		10	D1
35	l6-534006g\l6-0767.wiff	167-12	46664, 6-12 hr	Unknown			N/A	1.00	No Intercept	#BAD!	4.22e+008	5.34	Base To Base	☐		10	D1
36	l6-534006g\l6-0768.wiff	167-13	46664, 6-12 hr rinse	Unknown			N/A	1.00	No Intercept	#BAD!	6.26e+007	5.46	Base To Base	☐		10	D1
37	l6-534006g\l6-0769.wiff	167-14	46667, 6-12 hr	Unknown			N/A	1.00	No Intercept	#BAD!	4.31e+008	5.43	Base To Base	☐		10	D1
38	l6-534006g\l6-0770.wiff	167-15	46667, 6-12 hr rinse	Unknown			N/A	1.00	4263.3	N/A	4.56e+007	5.38	Base To Base	☐		10	D1
39	l6-534006g\l6-0771.wiff	167-16	46670, 6-12 hr	Unknown			N/A	1.00	No Intercept	#BAD!	3.73e+008	5.39	Base To Base	☐		10	D1
40	l6-534006g\l6-0772.wiff	167-17	46670, 6-12 hr rinse	Unknown			N/A	1.00	3269.5	N/A	3.85e+007	5.43	Base To Base	☐		10	D1
41	l6-534006g\l6-0773.wiff	168a-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	D1
42	l6-534006g\l6-0774.wiff	164-2	C 10	Standard		☒	10.000	1.00	10.600	6.0	2.40e+005	5.56	Base To Base	☐		10	E3
43	l6-534006g\l6-0775.wiff	164-5	C 30	Standard		☒	30.000	1.00	27.309	-9.0	4.96e+005	5.55	Base To Base	☐		10	F3
44	l6-534006g\l6-0776.wiff	164-8	C 100	Standard		☒	100.00	1.00	107.61	7.6	1.71e+006	5.57	Base To Base	☐		10	B4
45	l6-534006g\l6-0777.wiff	164-11	C 300	Standard		☒	300.00	1.00	325.42	8.5	4.94e+006	5.57	Base To Base	☐		10	E4
46	l6-534006g\l6-0778.wiff	164-14	C 1000	Standard		☒	1000.0	1.00	1021.5	2.2	1.46e+007	5.51	Base To Base	☐		10	G4
47	l6-534006g\l6-0779.wiff	168a-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	C6
48	l6-534006g\l6-0780.wiff	165-2	QC 30	Quality Control		☒	30.000	1.00	25.751	-14.	4.72e+005	5.59	Base To Base	☐		10	E6
49	l6-534006g\l6-0781.wiff	165-5	QC 250	Quality Control		☒	250.00	1.00	206.04	-18.	3.19e+006	5.59	Base To Base	☐		10	G6
50	l6-534006g\l6-0782.wiff	165-8	QC 750	Quality Control		☒	750.00	1.00	775.35	3.4	1.13e+007	5.57	Base To Base	☐		10	D7
51	l6-534006g\l6-0783.wiff	165-11	QC 10000	Quality Control		☒	10000.	20.0	9624.3	-3.8	7.19e+006	5.59	Base To Base	☐		10	A7
52	l6-534006g\l6-0784.wiff	168a-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	D1
53	l6-534006g\l6-0785.wiff	167-18	46682, 6-12 hr	Unknown			N/A	1.00	No Intercept	#BAD!	1.14e+008	5.52	Base To Base	☐		10	D1
54	l6-534006g\l6-0786.wiff	167-19	46682, 6-12 hr rinse	Unknown			N/A	1.00	671.40	N/A	9.86e+006	5.50	Base To Base	☐		10	D1
55	l6-534006g\l6-0787.wiff	167-20	46683, 6-12 hr	Unknown			N/A	1.00	No Intercept	#BAD!	3.42e+008	5.53	Base To Base	☐		10	D1
56	l6-534006g\l6-0788.wiff	167-21	46683, 6-12 hr rinse	Unknown			N/A	1.00	3042.0	N/A	3.66e+007	5.44	Base To Base	☐		10	D1
57	l6-534006g\l6-0789.wiff	167-22	46690, 6-12 hr	Unknown			N/A	1.00	No Intercept	#BAD!	3.75e+008	5.55	Base To Base	☐		10	D1
58	l6-534006g\l6-0790.wiff	167-23	46690, 6-12 hr rinse	Unknown			N/A	1.00	1813.9	N/A	2.43e+007	5.51	Base To Base	☐		10	D1
59	l6-534006g\l6-0791.wiff	168-1	46664, 12-24 hr	Unknown			N/A	1.00	No Intercept	#BAD!	1.45e+008	5.53	Base To Base	☐		10	D1
60	l6-534006g\l6-0792.wiff	168-2	46664, 12-24 hr rinse	Unknown			N/A	1.00	752.56	N/A	1.10e+007	5.46	Base To Base	☐		10	D1
61	l6-534006g\l6-0793.wiff	168-3	46667, 12-24 hr	Unknown			N/A	1.00	No Intercept	#BAD!	1.69e+008	5.57	Base To Base	☐		10	D1
62	l6-534006g\l6-0794.wiff	168-4	46667, 12-24 hr rinse	Unknown			N/A	1.00	1390.8	N/A	1.93e+007	5.46	Base To Base	☐		10	D1
63	l6-534006g\l6-0795.wiff	168-5	46670, 12-24 hr	Unknown			N/A	1.00	No Intercept	#BAD!	1.36e+008	5.59	Base To Base	☐		10	D1
64	l6-534006g\l6-0796.wiff	168-6	46670, 12-24 hr rinse	Unknown			N/A	1.00	632.46	N/A	9.32e+006	5.47	Valley	☐		10	D1
65	l6-534006g\l6-0797.wiff	168-7	46682, 12-24 hr	Unknown			N/A	1.00	1258.1	N/A	1.76e+007	5.61	Base To Base	☐		10	D1

	File Name	Sample ID	Sample Name	Sample Type	Analyte Peak Name	Use Record	Analyte Concentration (ng/mL)	Dilution Factor	Calculated Concentration (ng/mL)	%RE	Analyte Peak Area (counts)	Analyte Retention Time (min)	Analyte Integration Type	Record Modified	Sample Annotation	LCARTRIDGETRAY	LCARTRIDGEPOSITION
66	I6-534006g\I6-0798.wiff	168-8	46682, 12-24 hr rinse	Unknown			N/A	1.00	238.01	N/A	3.66e+006	5.51	Base To Base	☐		10	D1
67	I6-534006g\I6-0799.wiff	168-9	46683, 12-24 hr	Unknown			N/A	1.00	1100.8	N/A	1.56e+007	5.58	Base To Base	☐		10	D1
68	I6-534006g\I6-0800.wiff	168-10	46683, 12-24 hr rinse	Unknown			N/A	1.00	342.42	N/A	5.19e+006	5.48	Base To Base	☐		10	D1
69	I6-534006g\I6-0801.wiff	168-11	46690, 12-24 hr	Unknown			N/A	1.00	616.33	N/A	9.10e+006	5.60	Base To Base	☐		10	D1
70	I6-534006g\I6-0802.wiff	168-12	46690, 12-24 hr rinse	Unknown			N/A	1.00	122.72	N/A	1.94e+006	5.49	Base To Base	☐		10	D1
71	I6-534006g\I6-0803.wiff	168a-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	C6
72	I6-534006g\I6-0804.wiff	165-3	QC 30	Quality Control		☒	30.000	1.00	28.295	-5.7	5.11e+005	5.58	Base To Base	☐		10	E6
73	I6-534006g\I6-0805.wiff	165-6	QC 250	Quality Control		☒	250.00	1.00	217.17	-13.	3.35e+006	5.65	Base To Base	☐		10	G6
74	I6-534006g\I6-0806.wiff	165-9	QC 750	Quality Control		☒	750.00	1.00	755.20	0.69	1.10e+007	5.65	Base To Base	☐		10	D7
75	I6-534006g\I6-0807.wiff	165-12	QC 10000	Quality Control		☒	10000.	20.0	9656.7	-3.4	7.21e+006	5.56	Base To Base	☐		10	A7
76	I6-534006g\I6-0808.wiff	168a-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	D1
77	I6-534006g\I6-0809.wiff	164-3	C 10	Standard		☒	10.000	1.00	8.4934	-15.	2.08e+005	5.46	Base To Base	☐		10	E3
78	I6-534006g\I6-0810.wiff	164-6	C 30	Standard		☒	30.000	1.00	27.228	-9.2	4.94e+005	5.62	Base To Base	☐		10	F3
79	I6-534006g\I6-0811.wiff	164-9	C 100	Standard		☒	100.00	1.00	100.59	0.59	1.61e+006	5.61	Base To Base	☐		10	B4
80	I6-534006g\I6-0812.wiff	164-12	C 300	Standard		☒	300.00	1.00	293.97	-2.0	4.48e+006	5.68	Base To Base	☐		10	E4
81	I6-534006g\I6-0813.wiff	164-15	C 1000	Standard		☒	1000.0	1.00	960.64	-3.9	1.38e+007	5.56	Base To Base	☐		10	G4

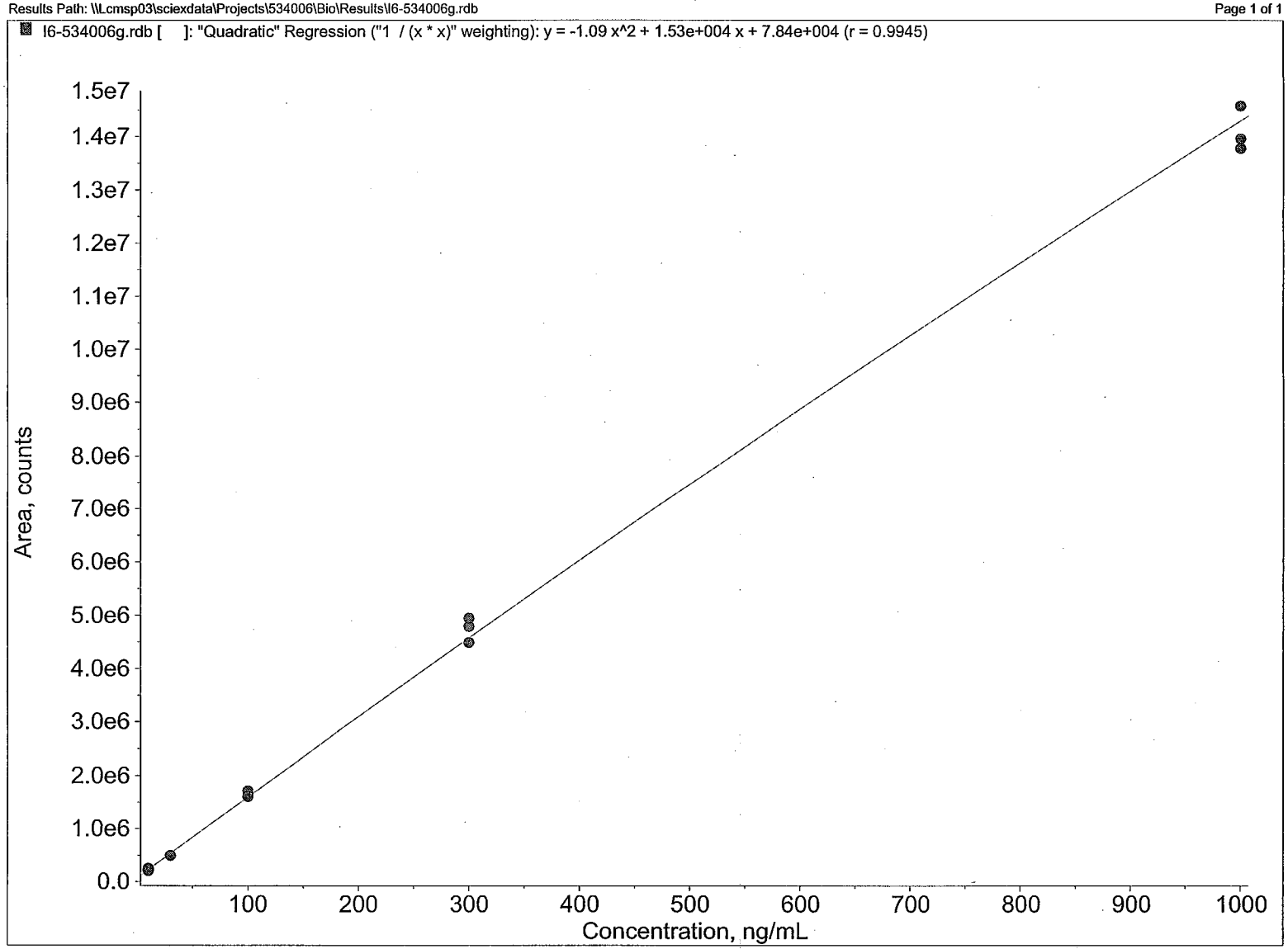

I6-534006g.rdb [ ]: "Quadratic" Regression ("1 / (x * x)" weighting): y = -1.09 x^2 + 1.53e+004 x + 7.84e+004 (r = 0.9945)
Area, counts
1.5e7
1.4e7
1.3e7
1.2e7
1.1e7
1.0e7
9.0e6
8.0e6
7.0e6
6.0e6
5.0e6
4.0e6
3.0e6
2.0e6
1.0e6
0.0
100
200
300
400
500
600
700
800
900
1000
Concentration, ng/mL

Table A-10: I6-534006j Data

Note:
Experimental serum samples

Study Record Page: 201a

Results Path: \\Lcmsp03\sciexdata\Projects\534006\Bio\Results\I6-534006j.rdb

	File Name	Sample ID	Sample Name	Sample Type	Analyte Peak Name	Use Record	Analyte Concentration (ng/mL)	Dilution Factor	Calculated Concentration (ng/mL)	%RE	Analyte Peak Area (counts)	Analyte Retention Time (min)	Analyte Integration Type	Record Modified	Sample Annotation
1	I6-534006j\I6-1018.wiff	190-10	Test Solution	Unknown			N/A	1.00	1470.8	N/A	2.42e+007	5.81	Base To Base	☐	
2	I6-534006j\I6-1019.wiff	190-10	Test Solution	Unknown			N/A	1.00	1512.7	N/A	2.47e+007	5.70	Base To Base	☒	peak tailing factor
3	I6-534006j\I6-1020.wiff	190-10	Test Solution	Unknown			N/A	1.00	1583.3	N/A	2.55e+007	5.69	Valley	☐	
4	I6-534006j\I6-1021.wiff	190-10	Test Solution	Unknown			N/A	1.00	1660.4	N/A	2.64e+007	5.62	Base To Base	☐	
5	I6-534006j\I6-1022.wiff	190-10	Test Solution	Unknown			N/A	1.00	1739.0	N/A	2.72e+007	5.63	Base To Base	☐	
6	I6-534006j\I6-1023.wiff	190-10	Test Solution	Unknown			N/A	1.00	1872.2	N/A	2.85e+007	5.57	Base To Base	☐	
7	I6-534006j\I6-1024.wiff	190-10	Test Solution	Unknown			N/A	1.00	1882.1	N/A	2.86e+007	5.54	Base To Base	☐	
8	I6-534006j\I6-1025.wiff	190-10	Test Solution	Unknown			N/A	1.00	1969.0	N/A	2.94e+007	5.51	Base To Base	☐	
9	I6-534006j\I6-1026.wiff	190-10	Test Solution	Unknown			N/A	1.00	2088.8	N/A	3.04e+007	5.45	Base To Base	☒	peak tailing factor
10	I6-534006j\I6-1027.wiff	190-10	Test Solution	Unknown			N/A	1.00	2186.0	N/A	3.12e+007	5.42	Base To Base	☐	
11	I6-534006j\I6-1028.wiff	188-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
12	I6-534006j\I6-1029.wiff	194-1	Solvent Blank	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
13	I6-534006j\I6-1030.wiff	194-2	Blank Serum	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
14	I6-534006j\I6-1031.wiff	194-3	Blank Serum	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
15	I6-534006j\I6-1032.wiff	194-4	Blank Serum	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
16	I6-534006j\I6-1033.wiff	188-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
17	I6-534006j\I6-1034.wiff	192-1	C 10	Standard		☒	10.000	1.00	8.6731	-13.	2.18e+005	5.13	Base To Base	☐	
18	I6-534006j\I6-1035.wiff	192-4	C 30	Standard		☒	30.000	1.00	26.882	-10.	5.98e+005	4.94	Base To Base	☐	
19	I6-534006j\I6-1036.wiff	192-7	C 100	Standard		☒	100.00	1.00	96.152	-3.8	2.03e+006	4.97	Base To Base	☐	
20	I6-534006j\I6-1037.wiff	192-10	C 300	Standard		☒	300.00	1.00	269.80	-10.	5.47e+006	5.01	Base To Base	☐	
21	I6-534006j\I6-1038.wiff	192-13	C 500	Standard		☒	500.00	1.00	464.53	-7.1	9.12e+006	4.95	Base To Base	☐	
22	I6-534006j\I6-1039.wiff	192-16	C 750	Standard		☒	750.00	1.00	713.59	-4.9	1.34e+007	4.89	Base To Base	☐	
23	I6-534006j\I6-1040.wiff	192-19	C 1000	Standard		☒	1000.0	1.00	963.22	-3.7	1.74e+007	4.87	Base To Base	☐	
24	I6-534006j\I6-1041.wiff	188-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
25	I6-534006j\I6-1042.wiff	193-1	QC 30	Quality Control		☒	30.000	1.00	28.320	-5.6	6.28e+005	4.91	Valley	☐	
26	I6-534006j\I6-1043.wiff	193-4	QC 250	Quality Control		☒	250.00	1.00	235.59	-5.8	4.81e+006	4.90	Base To Base	☐	
27	I6-534006j\I6-1044.wiff	193-7	QC 750	Quality Control		☒	750.00	1.00	732.32	-2.4	1.38e+007	4.93	Base To Base	☐	
28	I6-534006j\I6-1045.wiff	193-10	QC 30000	Quality Control		☒	30000.	1000.	27980.	-6.7	6.21e+005	4.84	Base To Base	☐	
29	I6-534006j\I6-1046.wiff	188-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
30	I6-534006j\I6-1047.wiff	195-1	46662,D0,1M,T0	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
31	I6-534006j\I6-1048.wiff	195-2	46663,D0,1M,T0	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
32	I6-534006j\I6-1049.wiff	195-3	46665,D0,1M,T0	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
33	I6-534006j\I6-1050.wiff	195-4	46678,D0,1F,T0	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
34	I6-534006j\I6-1051.wiff	195-5	46679,D0,1F,T0	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
35	I6-534006j\I6-1052.wiff	195-6	46680,D0,1F,T0	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
36	I6-534006j\I6-1053.wiff	196-1	46666,D0,1M,T2 min	Unknown			N/A	1000.	85509.	N/A	1.81e+006	4.89	Base To Base	☐	
37	I6-534006j\I6-1054.wiff	196-2	46669,D0,1M,T2 min	Unknown			N/A	1000.	16736.	N/A	3.87e+005	4.78	Base To Base	☐	
38	I6-534006j\I6-1055.wiff	196-3	46672,D0,1M,T2 min	Unknown			N/A	1000.	100720.	N/A	2.12e+006	4.84	Base To Base	☐	
39	I6-534006j\I6-1056.wiff	196-4	46681,D0,1F,T2 min	Unknown			N/A	1000.	88738.	N/A	1.87e+006	4.84	Base To Base	☐	
40	I6-534006j\I6-1057.wiff	196-5	46684,D0,1F,T2 min	Unknown			N/A	1000.	98125.	N/A	2.07e+006	4.85	Base To Base	☐	
41	I6-534006j\I6-1058.wiff	196-6	46685,D0,1F,T2 min	Unknown			N/A	1000.	97362.	N/A	2.05e+006	4.84	Valley	☐	
42	I6-534006j\I6-1059.wiff	196-7	46673,D0,1M,T10min	Unknown			N/A	1000.	71736.	N/A	1.53e+006	4.84	Base To Base	☐	
43	I6-534006j\I6-1060.wiff	196-8	46674,D0,1M,T10min	Unknown			N/A	1000.	59438.	N/A	1.27e+006	4.78	Base To Base	☐	
44	I6-534006j\I6-1061.wiff	196-9	46676,D0,1M,T10min	Unknown			N/A	1000.	76212.	N/A	1.62e+006	4.80	Base To Base	☐	
45	I6-534006j\I6-1062.wiff	196-10	46686,D0,1F,T10min	Unknown			N/A	1000.	53064.	N/A	1.14e+006	4.78	Base To Base	☐	
46	I6-534006j\I6-1063.wiff	196-11	46688,D0,1F,T10min	Unknown			N/A	1000.	43359.	N/A	9.40e+005	4.81	Base To Base	☐	
47	I6-534006j\I6-1064.wiff	196-12	46691,D0,1F,T10min	Unknown			N/A	1000.	54242.	N/A	1.17e+006	4.68	Base To Base	☐	
48	I6-534006j\I6-1065.wiff	196-13	46662,D0,1M,T20 min	Unknown			N/A	1000.	65371.	N/A	1.39e+006	4.77	Base To Base	☐	
49	I6-534006j\I6-1066.wiff	196-14	46663,D0,1M,T20 min	Unknown			N/A	1000.	55817.	N/A	1.20e+006	4.75	Base To Base	☐	
50	I6-534006j\I6-1067.wiff	196-15	46665,D0,1M,T20 min	Unknown			N/A	1000.	65870.	N/A	1.41e+006	4.76	Base To Base	☐	
51	I6-534006j\I6-1068.wiff	196-16	46678,D0,1F,T20 min	Unknown			N/A	1000.	30804.	N/A	6.80e+005	4.73	Base To Base	☒	peak tailing factor
52	I6-534006j\I6-1069.wiff	196-17	46679,D0,1F,T20 min	Unknown			N/A	1000.	27712.	N/A	6.16e+005	4.72	Base To Base	☐	
53	I6-534006j\I6-1070.wiff	196-18	46680,D0,1F,T20 min	Unknown			N/A	1000.	31506.	N/A	6.94e+005	4.74	Base To Base	☐	
54	I6-534006j\I6-1071.wiff	188-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
55	I6-534006j\I6-1072.wiff	192-2	C 10	Standard		☒	10.000	1.00	10.445	4.5	2.55e+005	4.75	Base To Base	☐	
56	I6-534006j\I6-1073.wiff	192-5	C 30	Standard		☒	30.000	1.00	33.657	12.	7.39e+005	4.75	Base To Base	☐	
57	I6-534006j\I6-1074.wiff	192-8	C 100	Standard		☒	100.00	1.00	99.328	-0.67	2.09e+006	4.75	Base To Base	☐	
58	I6-534006j\I6-1075.wiff	192-11	C 300	Standard		☒	300.00	1.00	298.41	-0.53	6.02e+006	4.66	Base To Base	☐	

Printing Date: Tuesday, March 27, 2007

Operator: Shelley Hollar

	File Name	Sample ID	Sample Name	Sample Type	Analyte Peak Name	Use Record	Analyte Concentration (ng/mL)	Dilution Factor	Calculated Concentration (ng/mL)	%RE	Analyte Peak Area (counts)	Analyte Retention Time (min)	Analyte Integration Type	Record Modified	Sample Annotation
59	I6-534006j\I6-1076.wiff	192-14	C 500	Standard		☒	500.00	1.00	499.45	-0.11	9.75e+006	4.69	Base To Base	☐	
60	I6-534006j\I6-1077.wiff	192-17	C 750	Standard		☒	750.00	1.00	763.47	1.8	1.43e+007	4.63	Base To Base	☐	
61	I6-534006j\I6-1078.wiff	192-20	C 1000	Standard		☒	1000.0	1.00	1004.9	0.49	1.80e+007	4.67	Base To Base	☐	
62	I6-534006j\I6-1079.wiff	188-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
63	I6-534006j\I6-1080.wiff	193-2	QC 30	Quality Control		☒	30.000	1.00	30.544	1.8	6.74e+005	4.67	Base To Base	☐	
64	I6-534006j\I6-1081.wiff	193-5	QC 250	Quality Control		☒	250.00	1.00	242.87	-2.9	4.95e+006	4.69	Base To Base	☐	
65	I6-534006j\I6-1082.wiff	193-8	QC 750	Quality Control		☒	750.00	1.00	735.43	-1.9	1.38e+007	4.65	Base To Base	☐	
66	I6-534006j\I6-1083.wiff	193-11	QC 30000	Quality Control		☒	30000.	1000.	30449.	1.5	6.72e+005	4.66	Base To Base	☐	
67	I6-534006j\I6-1084.wiff	188-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
68	I6-534006j\I6-1085.wiff	197-1	46666,D0,1M,T30 min	Unknown			N/A	1000.	51702.	N/A	1.11e+006	4.64	Base To Base	☐	
69	I6-534006j\I6-1086.wiff	197-2	46669,D0,1M,T30 min	Unknown			N/A	1000.	19975.	N/A	4.54e+005	4.68	Base To Base	☐	
70	I6-534006j\I6-1087.wiff	197-3	46672,D0,1M,T30 min	Unknown			N/A	1000.	57560.	N/A	1.23e+006	4.73	Base To Base	☐	
71	I6-534006j\I6-1088.wiff	197-4	46681,D0,1F,T30 min	Unknown			N/A	1000.	27329.	N/A	6.08e+005	4.66	Base To Base	☐	
72	I6-534006j\I6-1089.wiff	197-5	46684,D0,1F,T30 min	Unknown			N/A	1000.	24091.	N/A	5.40e+005	4.76	Base To Base	☐	
73	I6-534006j\I6-1090.wiff	197-6	46685,D0,1F,T30 min	Unknown			N/A	1000.	19724.	N/A	4.49e+005	4.68	Base To Base	☐	
74	I6-534006j\I6-1091.wiff	197-7	46673,D0,1M,T1 hr	Unknown			N/A	1000.	62374.	N/A	1.33e+006	4.72	Base To Base	☐	
75	I6-534006j\I6-1092.wiff	197-8	46674,D0,1M,T1 hr	Unknown			N/A	1000.	47426.	N/A	1.02e+006	4.70	Base To Base	☐	
76	I6-534006j\I6-1093.wiff	197-9	46676,D0,1M,T1 hr	Unknown			N/A	1000.	81376.	N/A	1.72e+006	4.68	Base To Base	☐	
77	I6-534006j\I6-1094.wiff	197-10	46686,D0,1F,T1 hr	Unknown			N/A	1000.	15651.	N/A	3.64e+005	4.66	Base To Base	☐	
78	I6-534006j\I6-1095.wiff	197-11	46688,D0,1F,T1 hr	Unknown			N/A	1000.	7912.2	N/A	2.02e+005	4.67	Base To Base	☐	
79	I6-534006j\I6-1096.wiff	197-12	46691,D0,1F,T1 hr	Unknown			N/A	1000.	17595.	N/A	4.05e+005	4.73	Base To Base	☐	
80	I6-534006j\I6-1097.wiff	198-1	46662,D0,1M,T3 hr	Unknown			N/A	100.	37375.	N/A	7.45e+006	4.62	Base To Base	☐	
81	I6-534006j\I6-1098.wiff	198-2	46663,D0,1M,T3 hr	Unknown			N/A	100.	15238.	N/A	3.16e+006	4.64	Base To Base	☐	
82	I6-534006j\I6-1099.wiff	198-3	46665,D0,1M,T3 hr	Unknown			N/A	100.	22245.	N/A	4.55e+006	4.65	Base To Base	☐	
83	I6-534006j\I6-1100.wiff	198-4	46678,D0,1F,T3 hr	Unknown			N/A	100.	1028.0	N/A	2.52e+005	4.62	Base To Base	☐	
84	I6-534006j\I6-1101.wiff	198-5	46666,D0,1M,T5 hr	Unknown			N/A	100.	8626.8	N/A	1.82e+006	4.61	Base To Base	☐	
85	I6-534006j\I6-1102.wiff	198-6	46669,D0,1M,T5 hr	Unknown			N/A	100.	20677.	N/A	4.24e+006	4.66	Base To Base	☐	
86	I6-534006j\I6-1103.wiff	198-7	46672,D0,1M,T5 hr	Unknown			N/A	100.	17947.	N/A	3.70e+006	4.69	Base To Base	☐	
87	I6-534006j\I6-1104.wiff	198-8	46673,D0,1M,T7 hr	Unknown			N/A	100.	24227.	N/A	4.94e+006	4.67	Base To Base	☐	
88	I6-534006j\I6-1105.wiff	198-9	46674,D0,1M,T7 hr	Unknown			N/A	100.	7111.1	N/A	1.51e+006	4.61	Base To Base	☐	
89	I6-534006j\I6-1106.wiff	198-10	46676,D0,1M,T7 hr	Unknown			N/A	100.	20778.	N/A	4.26e+006	4.64	Base To Base	☐	
90	I6-534006j\I6-1107.wiff	201-2	Stock Stab	Unknown			N/A	1.00	1662.6	N/A	2.64e+007	4.68	Base To Base	☐	
91	I6-534006j\I6-1108.wiff	201-4	Stock Stab	Unknown			N/A	1.00	1636.1	N/A	2.61e+007	4.68	Base To Base	☐	
92	I6-534006j\I6-1109.wiff	201-6	Stock Stab	Unknown			N/A	1.00	1661.7	N/A	2.64e+007	4.69	Base To Base	☐	
93	I6-534006j\I6-1110.wiff	201-8	Stock Stab	Unknown			N/A	1.00	1683.4	N/A	2.66e+007	4.69	Base To Base	☐	
94	I6-534006j\I6-1111.wiff	188-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
95	I6-534006j\I6-1112.wiff	193-3	QC 30	Quality Control		☒	30.000	1.00	30.124	0.41	6.66e+005	4.66	Base To Base	☐	
96	I6-534006j\I6-1113.wiff	193-6	QC 250	Quality Control		☒	250.00	1.00	248.88	-0.45	5.07e+006	4.63	Base To Base	☐	
97	I6-534006j\I6-1114.wiff	193-9	QC 750	Quality Control		☒	750.00	1.00	742.94	-0.94	1.39e+007	4.65	Base To Base	☐	
98	I6-534006j\I6-1115.wiff	193-12	QC 30000	Quality Control		☒	30000.	1000.	30268.	0.89	6.69e+005	4.60	Base To Base	☐	
99	I6-534006j\I6-1116.wiff	188-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
100	I6-534006j\I6-1117.wiff	192-3	C 10	Standard		☒	10.000	1.00	10.500	5.0	2.56e+005	4.71	Base To Base	☐	
101	I6-534006j\I6-1118.wiff	192-6	C 30	Standard		☒	30.000	1.00	33.321	11.	7.32e+005	4.70	Base To Base	☐	
102	I6-534006j\I6-1119.wiff	192-9	C 100	Standard		☒	100.00	1.00	103.22	3.2	2.17e+006	4.72	Base To Base	☐	
103	I6-534006j\I6-1120.wiff	192-12	C 300	Standard		☒	300.00	1.00	302.10	0.70	6.09e+006	4.69	Base To Base	☐	
104	I6-534006j\I6-1121.wiff	192-15	C 500	Standard		☒	500.00	1.00	517.14	3.4	1.01e+007	4.68	Base To Base	☐	
105	I6-534006j\I6-1122.wiff	192-18	C 750	Standard		☒	750.00	1.00	794.40	5.9	1.48e+007	4.69	Base To Base	☐	
106	I6-534006j\I6-1123.wiff	192-21	C 1000	Standard		☒	1000.0	1.00	1068.8	6.9	1.89e+007	4.69	Base To Base	☐	

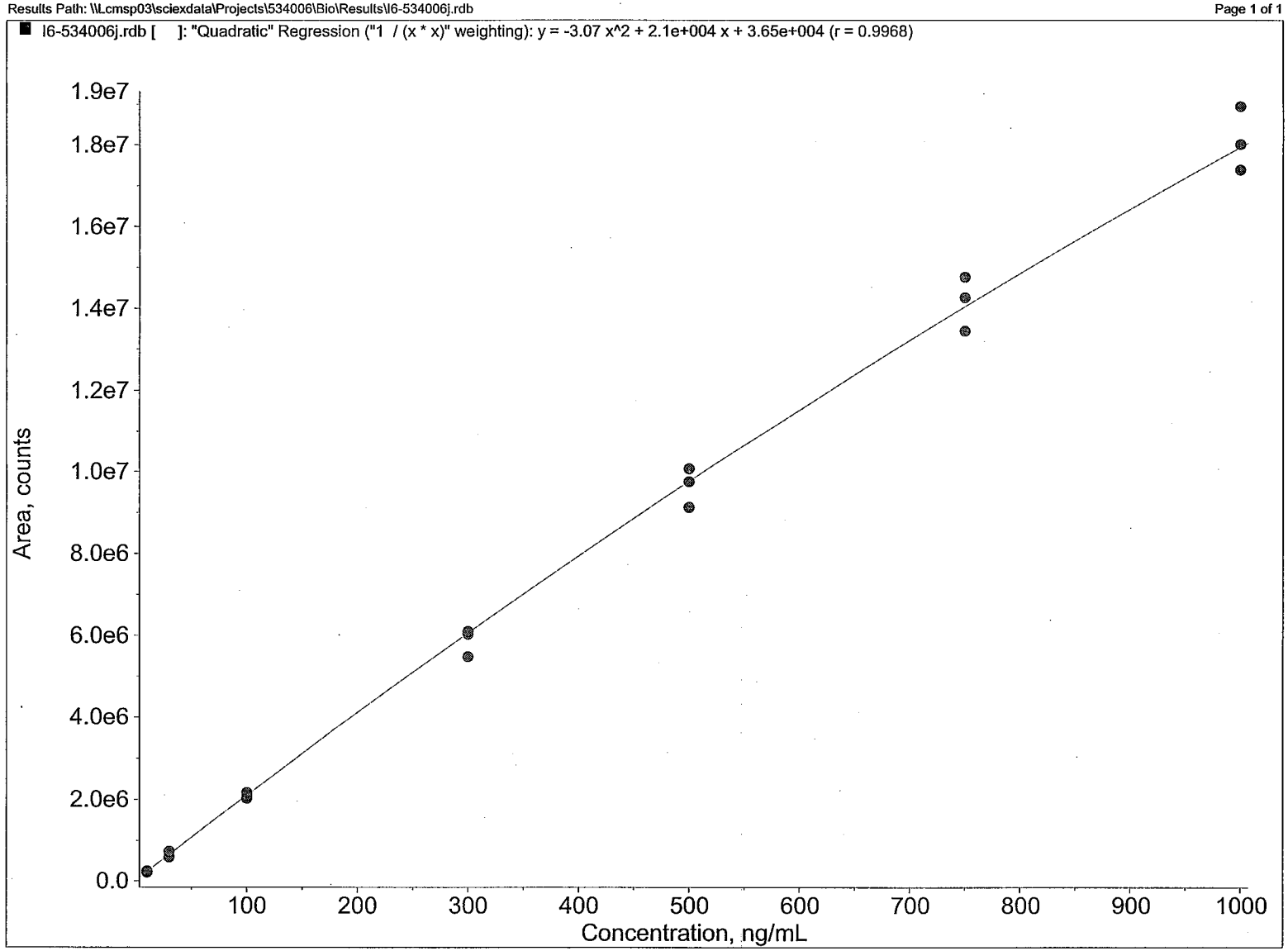

l6-534006j.rdb [ ]: "Quadratic" Regression ("1 / (x * x)" weighting): y = -3.07 x^2 + 2.1e+004 x + 3.65e+004 (r = 0.9968)
Area, counts
1.9e7
1.8e7
1.6e7
1.4e7
1.2e7
1.0e7
8.0e6
6.0e6
4.0e6
2.0e6
0.0
100
200
300
400
500
600
700
800
900
1000
Concentration, ng/mL

Table A-11: I6-534006k Data

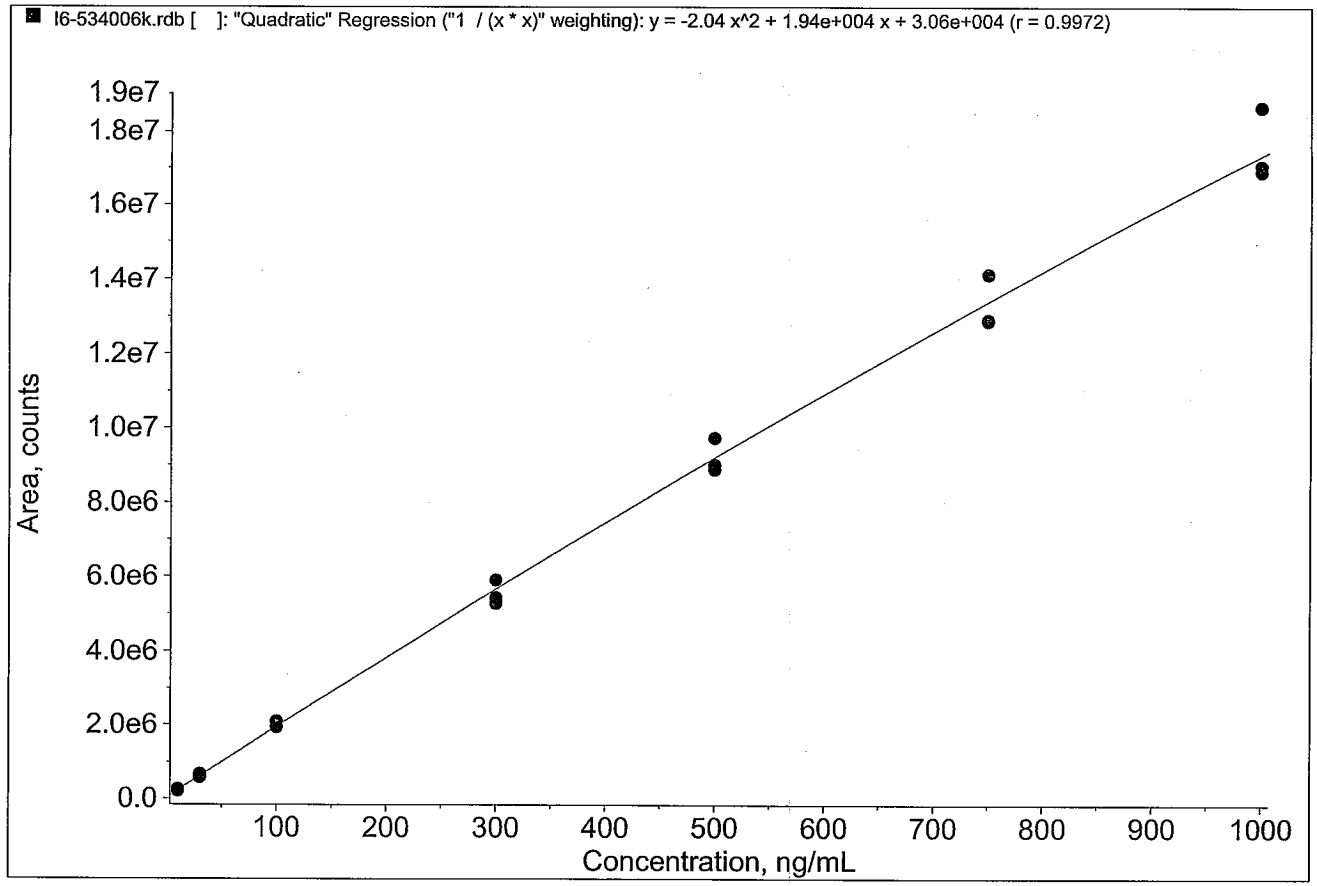
Note:
Experimental serum sample analysis
11-day long term frozen stability and 4 hour benchtop stability assessments

Study Record Page: 212a

	File Name	Sample ID	Sample Name	Sample Type	Analyte Peak Name	Use Record	Analyte Concentration (ng/mL)	Dilution Factor	Calculated Concentration (ng/mL)	%RE	Analyte Peak Area (counts)	Analyte Retention Time (min)	Analyte Integration Type	Record Modified	Sample Annotation
1	I6-534006k\I6-1124.wiff	203-10	Test Solution	Unknown			N/A	1.00	2391.2	N/A	3.47e+007	5.27	Base To Base	☐	
2	I6-534006k\I6-1125.wiff	203-10	Test Solution	Unknown			N/A	1.00	2494.8	N/A	3.56e+007	5.37	Base To Base	☐	
3	I6-534006k\I6-1126.wiff	203-10	Test Solution	Unknown			N/A	1.00	2510.0	N/A	3.58e+007	5.41	Base To Base	☐	
4	I6-534006k\I6-1127.wiff	203-10	Test Solution	Unknown			N/A	1.00	2594.9	N/A	3.65e+007	5.43	Base To Base	☐	
5	I6-534006k\I6-1128.wiff	203-10	Test Solution	Unknown			N/A	1.00	2631.4	N/A	3.69e+007	5.44	Base To Base	☐	
6	I6-534006k\I6-1129.wiff	203-10	Test Solution	Unknown			N/A	1.00	2645.6	N/A	3.70e+007	5.45	Base To Base	☐	
7	I6-534006k\I6-1130.wiff	203-10	Test Solution	Unknown			N/A	1.00	2687.3	N/A	3.73e+007	5.49	Base To Base	☐	
8	I6-534006k\I6-1131.wiff	203-10	Test Solution	Unknown			N/A	1.00	2778.9	N/A	3.81e+007	5.60	Base To Base	☐	
9	I6-534006k\I6-1132.wiff	203-10	Test Solution	Unknown			N/A	1.00	2817.1	N/A	3.84e+007	5.52	Base To Base	☐	
10	I6-534006k\I6-1133.wiff	203-10	Test Solution	Unknown			N/A	1.00	2793.5	N/A	3.82e+007	5.55	Base To Base	☐	
11	I6-534006k\I6-1134.wiff		Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
12	I6-534006k\I6-1135.wiff	207-1	Solvent Blank	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
13	I6-534006k\I6-1136.wiff	207-2	Blank Serum	Unknown			N/A	1.00	0.58423	N/A	4.19e+004	5.34	Base To Base	☐	
14	I6-534006k\I6-1137.wiff	207-3	Blank Serum	Unknown			N/A	1.00	0.43492	N/A	3.90e+004	5.49	Base To Base	☐	
15	I6-534006k\I6-1138.wiff	207-4	Blank Serum	Unknown			N/A	1.00	0.48626	N/A	4.00e+004	5.33	Base To Base	☐	
16	I6-534006k\I6-1139.wiff		Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
17	I6-534006k\I6-1140.wiff	205-1	C 10	Standard		☒	10.000	1.00	9.6359	-3.6	2.17e+005	5.51	Base To Base	☐	
18	I6-534006k\I6-1141.wiff	205-4	C 30	Standard		☒	30.000	1.00	29.916	-0.28	6.08e+005	5.42	Base To Base	☐	
19	I6-534006k\I6-1142.wiff	205-7	C 100	Standard		☒	100.00	1.00	98.972	-1.0	1.93e+006	5.41	Base To Base	☐	
20	I6-534006k\I6-1143.wiff	205-10	C 300	Standard		☒	300.00	1.00	286.86	-4.4	5.41e+006	5.39	Valley	☐	
21	I6-534006k\I6-1144.wiff	205-13	C 500	Standard		☒	500.00	1.00	488.28	-2.3	8.99e+006	5.40	Base To Base	☐	
22	I6-534006k\I6-1145.wiff	205-16	C 750	Standard		☒	750.00	1.00	719.77	-4.0	1.29e+007	5.38	Base To Base	☐	
23	I6-534006k\I6-1146.wiff	205-19	C 1000	Standard		☒	1000.0	1.00	981.41	-1.9	1.71e+007	5.42	Base To Base	☐	
24	I6-534006k\I6-1147.wiff		Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
25	I6-534006k\I6-1148.wiff	206-1	QC 30	Quality Control		☒	30.000	1.00	30.757	2.5	6.24e+005	5.44	Base To Base	☐	
26	I6-534006k\I6-1149.wiff	206-4	QC 250	Quality Control		☒	250.00	1.00	245.68	-1.7	4.66e+006	5.37	Base To Base	☐	
27	I6-534006k\I6-1150.wiff	206-7	QC 750	Quality Control		☒	750.00	1.00	734.37	-2.1	1.31e+007	5.39	Base To Base	☐	
28	I6-534006k\I6-1151.wiff	206-10	QC 30000	Quality Control		☒	30000.	100.	29723.	-0.92	5.60e+006	5.36	Base To Base	☐	
29	I6-534006k\I6-1152.wiff		Mobile Phase	Unknown			N/A	1.00	< 0	#BAD!	1.43e+004	5.43	Base To Base	☐	
30	I6-534006k\I6-1153.wiff	208-1	46688,D0,1F,T1	Unknown			N/A	100.	10027.	N/A	1.95e+006	5.35	Base To Base	☐	
31	I6-534006k\I6-1154.wiff		Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
32	I6-534006k\I6-1155.wiff	209-1	LT Stb 30 ng/mL	Unknown			N/A	1.00	30.493	N/A	6.19e+005	5.38	Base To Base	☐	
33	I6-534006k\I6-1156.wiff	209-2	LT Stb 30 ng/mL	Unknown			N/A	1.00	31.482	N/A	6.38e+005	5.36	Base To Base	☐	
34	I6-534006k\I6-1157.wiff	209-3	LT Stb 30 ng/mL	Unknown			N/A	1.00	30.472	N/A	6.18e+005	5.33	Base To Base	☐	
35	I6-534006k\I6-1158.wiff	209-4	LT Stb 750 ng/mL	Unknown			N/A	1.00	772.64	N/A	1.38e+007	5.33	Base To Base	☐	
36	I6-534006k\I6-1159.wiff	209-5	LT Stb 750 ng/mL	Unknown			N/A	1.00	759.55	N/A	1.36e+007	5.34	Base To Base	☐	
37	I6-534006k\I6-1160.wiff	209-6	LT Stb 750 ng/mL	Unknown			N/A	1.00	763.98	N/A	1.36e+007	5.39	Base To Base	☐	
38	I6-534006k\I6-1161.wiff		Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
39	I6-534006k\I6-1162.wiff	205-2	C 10	Standard		☒	10.000	1.00	8.9138	-11.	2.03e+005	5.33	Base To Base	☐	
40	I6-534006k\I6-1163.wiff	205-5	C 30	Standard		☒	30.000	1.00	27.780	-7.4	5.67e+005	5.30	Base To Base	☐	
41	I6-534006k\I6-1164.wiff	205-8	C 100	Standard		☒	100.00	1.00	98.612	-1.4	1.92e+006	5.34	Base To Base	☐	
42	I6-534006k\I6-1165.wiff	205-11	C 300	Standard		☒	300.00	1.00	278.75	-7.1	5.27e+006	5.28	Base To Base	☐	
43	I6-534006k\I6-1166.wiff	205-14	C 500	Standard		☒	500.00	1.00	481.28	-3.7	8.87e+006	5.33	Base To Base	☐	
44	I6-534006k\I6-1167.wiff	205-17	C 750	Standard		☒	750.00	1.00	718.19	-4.2	1.29e+007	5.27	Base To Base	☐	
45	I6-534006k\I6-1168.wiff	205-20	C 1000	Standard		☒	1000.0	1.00	970.81	-2.9	1.69e+007	5.31	Base To Base	☐	
46	I6-534006k\I6-1169.wiff		Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
47	I6-534006k\I6-1170.wiff	206-2	QC 30	Quality Control		☒	30.000	1.00	30.556	1.9	6.20e+005	5.26	Base To Base	☐	
48	I6-534006k\I6-1171.wiff	206-5	QC 250	Quality Control		☒	250.00	1.00	242.13	-3.1	4.60e+006	5.30	Base To Base	☐	
49	I6-534006k\I6-1172.wiff	206-8	QC 750	Quality Control		☒	750.00	1.00	746.88	-0.42	1.33e+007	5.33	Base To Base	☐	
50	I6-534006k\I6-1173.wiff	206-11	QC 30000	Quality Control		☒	30000.	100.	28014.	-6.6	5.29e+006	5.29	Base To Base	☐	
51	I6-534006k\I6-1174.wiff		Mobile Phase	Unknown			N/A	1.00	< 0	#BAD!	1.45e+004	5.25	Base To Base	☐	
52	I6-534006k\I6-1175.wiff	210-1	4 Hr Stb 30 ng/mL	Unknown			N/A	1.00	30.236	N/A	6.14e+005	5.30	Base To Base	☐	
53	I6-534006k\I6-1176.wiff	210-2	4 Hr Stb 30 ng/mL	Unknown			N/A	1.00	30.396	N/A	6.17e+005	5.30	Base To Base	☐	
54	I6-534006k\I6-1177.wiff	210-3	4 Hr Stb 30 ng/mL	Unknown			N/A	1.00	30.575	N/A	6.20e+005	5.32	Base To Base	☐	
55	I6-534006k\I6-1178.wiff	210-4	4 Hr Stb 750 ng/mL	Unknown			N/A	1.00	762.58	N/A	1.36e+007	5.32	Base To Base	☐	
56	I6-534006k\I6-1179.wiff	210-5	4 Hr Stb 750 ng/mL	Unknown			N/A	1.00	772.25	N/A	1.38e+007	5.33	Base To Base	☐	
57	I6-534006k\I6-1180.wiff	210-6	4 Hr Stb 750 ng/mL	Unknown			N/A	1.00	755.26	N/A	1.35e+007	5.24	Base To Base	☐	
58	I6-534006k\I6-1181.wiff		Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	

	File Name	Sample ID	Sample Name	Sample Type	Analyte Peak Name	Use Record	Analyte Concentration (ng/mL)	Dilution Factor	Calculated Concentration (ng/mL)	%RE	Analyte Peak Area (counts)	Analyte Retention Time (min)	Analyte Integration Type	Record Modified	Sample Annotation
59	I6-534006k\I6-1182.wiff	193-1	QC 30	Unknown			N/A	1.00	38.134	N/A	7.66e+005	5.36	Base To Base	☐	
60	I6-534006k\I6-1183.wiff	193-2	QC 30	Unknown			N/A	1.00	36.120	N/A	7.27e+005	5.36	Base To Base	☐	
61	I6-534006k\I6-1184.wiff	193-3	QC 30	Unknown			N/A	1.00	35.753	N/A	7.20e+005	5.42	Base To Base	☐	
62	I6-534006k\I6-1185.wiff	193-4	QC 250	Unknown			N/A	1.00	301.70	N/A	5.68e+006	5.38	Base To Base	☐	
63	I6-534006k\I6-1186.wiff	193-5	QC 250	Unknown			N/A	1.00	297.31	N/A	5.60e+006	5.35	Base To Base	☐	
64	I6-534006k\I6-1187.wiff	193-6	QC 250	Unknown			N/A	1.00	293.31	N/A	5.53e+006	5.30	Base To Base	☐	
65	I6-534006k\I6-1188.wiff	193-7	QC 750	Unknown			N/A	1.00	884.01	N/A	1.55e+007	5.35	Base To Base	☐	
66	I6-534006k\I6-1189.wiff	193-8	QC 750	Unknown			N/A	1.00	877.09	N/A	1.54e+007	5.29	Base To Base	☐	
67	I6-534006k\I6-1190.wiff	193-9	QC 750	Unknown			N/A	1.00	868.73	N/A	1.53e+007	5.23	Base To Base	☐	
68	I6-534006k\I6-1191.wiff	193-10	QC 30000	Unknown			N/A	1000.	35970.	N/A	7.24e+005	5.27	Base To Base	☐	
69	I6-534006k\I6-1192.wiff	193-11	QC 30000	Unknown			N/A	1000.	37506.	N/A	7.54e+005	5.28	Base To Base	☐	
70	I6-534006k\I6-1193.wiff	193-12	QC 30000	Unknown			N/A	1000.	37151.	N/A	7.47e+005	5.30	Base To Base	☐	
71	I6-534006k\I6-1194.wiff		Mobile Phase	Unknown			N/A	1.00	< 0	#BAD!	1.71e+004	5.35	Base To Base	☐	
72	I6-534006k\I6-1195.wiff	155-1	QC 30	Unknown			N/A	1.00	166.76	N/A	3.20e+006	5.31	Base To Base	☐	
73	I6-534006k\I6-1196.wiff	155-2	QC 30	Unknown			N/A	1.00	67.131	N/A	1.32e+006	5.38	Base To Base	☐	
74	I6-534006k\I6-1197.wiff	155-3	QC 30	Unknown			N/A	1.00	62.723	N/A	1.24e+006	5.32	Base To Base	☐	
75	I6-534006k\I6-1198.wiff	155-4	QC 250	Unknown			N/A	1.00	535.08	N/A	9.80e+006	5.34	Base To Base	☐	
76	I6-534006k\I6-1199.wiff	155-5	QC 250	Unknown			N/A	1.00	492.76	N/A	9.07e+006	5.33	Base To Base	☐	
77	I6-534006k\I6-1200.wiff	155-6	QC 250	Unknown			N/A	1.00	540.93	N/A	9.90e+006	5.37	Base To Base	☐	
78	I6-534006k\I6-1201.wiff	155-7	QC 750	Unknown			N/A	1.00	1721.7	N/A	2.73e+007	5.32	Base To Base	☐	
79	I6-534006k\I6-1202.wiff	155-8	QC 750	Unknown			N/A	1.00	1794.3	N/A	2.82e+007	5.34	Base To Base	☐	
80	I6-534006k\I6-1203.wiff	155-9	QC 750	Unknown			N/A	1.00	1707.3	N/A	2.71e+007	5.31	Base To Base	☐	
81	I6-534006k\I6-1204.wiff	155-10	QC 10000	Unknown			N/A	20.0	21073.	N/A	1.82e+007	5.34	Base To Base	☐	
82	I6-534006k\I6-1205.wiff	155-11	QC 10000	Unknown			N/A	20.0	23424.	N/A	1.99e+007	5.29	Base To Base	☐	
83	I6-534006k\I6-1206.wiff	155-12	QC 10000	Unknown			N/A	20.0	23338.	N/A	1.98e+007	5.32	Base To Base	☐	
84	I6-534006k\I6-1207.wiff		Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
85	I6-534006k\I6-1208.wiff	206-3	QC 30	Quality Control		☒	30.000	1.00	32.445	8.2	6.56e+005	5.13	Base To Base	☐	
86	I6-534006k\I6-1209.wiff	206-6	QC 250	Quality Control		☒	250.00	1.00	260.75	4.3	4.94e+006	5.08	Base To Base	☐	
87	I6-534006k\I6-1210.wiff	206-9	QC 750	Quality Control		☒	750.00	1.00	791.55	5.5	1.41e+007	5.09	Base To Base	☐	
88	I6-534006k\I6-1211.wiff	206-12	QC 30000	Quality Control		☒	30000.	100.	33381.	11.	6.26e+006	5.04	Base To Base	☐	
89	I6-534006k\I6-1212.wiff		Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
90	I6-534006k\I6-1213.wiff	205-3	C 10	Standard		☒	10.000	1.00	11.364	14.	2.50e+005	5.09	Base To Base	☐	
91	I6-534006k\I6-1214.wiff	205-6	C 30	Standard		☒	30.000	1.00	32.859	9.5	6.64e+005	5.11	Base To Base	☐	
92	I6-534006k\I6-1215.wiff	205-9	C 100	Standard		☒	100.00	1.00	107.24	7.2	2.08e+006	5.10	Base To Base	☐	
93	I6-534006k\I6-1216.wiff	205-12	C 300	Standard		☒	300.00	1.00	313.22	4.4	5.89e+006	5.04	Base To Base	☐	
94	I6-534006k\I6-1217.wiff	205-15	C 500	Standard		☒	500.00	1.00	530.29	6.1	9.72e+006	5.10	Base To Base	☐	
95	I6-534006k\I6-1218.wiff	205-18	C 750	Standard		☒	750.00	1.00	794.87	6.0	1.41e+007	5.17	Base To Base	☐	
96	I6-534006k\I6-1219.wiff	205-21	C 1000	Standard		☒	1000.0	1.00	1086.8	8.7	1.87e+007	5.17	Base To Base	☐	

Results Path: \\Lcmsp03\sciexdata\Projects\534006\Bio\Results\I6-534006k.rd
Results Name: I6-534006k.rdb



Printing Date: Wednesday, March 28, 2007
Printing Time: 9:38:57 AM

Operator: Shelley Hollar
nalyst Version: 1.4.2

Table A-12: I6-534006l1 Data

Note:
Experimental urine sample analysis

Study Record Page: 224b

	File Name	Sample ID	Sample Name	Sample Type	Analyte Peak Name	Use Record	Analyte Concentration (ng/mL)	Dilution Factor	Calculated Concentration (ng/mL)	%RE	Analyte Peak Area (counts)	Analyte Retention Time (min)	Analyte Integration Type	Record Modified	Sample Annotation	LCARTRIDGETRAY	LCARTRIDGEPOSITION
1	I6-534006I1\I6-1254.wiff	214-10	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	3.08e+007	5.93	Valley	☐		10	A1
2	I6-534006I1\I6-1255.wiff	214-10	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	2.98e+007	5.93	Base To Base	☐		10	B1
3	I6-534006I1\I6-1256.wiff	214-10	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	2.96e+007	5.94	Base To Base	☒	peak splitting factor	10	C1
4	I6-534006I1\I6-1257.wiff	214-10	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	2.96e+007	5.99	Base To Base	☐		10	C1
5	I6-534006I1\I6-1258.wiff	214-10	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	2.99e+007	5.98	Base To Base	☒	peak splitting factor	10	C1
6	I6-534006I1\I6-1259.wiff	214-10	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	3.02e+007	6.00	Base To Base	☐		10	A1
7	I6-534006I1\I6-1260.wiff	214-10	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	3.03e+007	6.01	Base To Base	☐		10	A1
8	I6-534006I1\I6-1261.wiff	214-10	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	3.02e+007	5.92	Base To Base	☐		10	A1
9	I6-534006I1\I6-1262.wiff	214-10	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	3.05e+007	5.99	Base To Base	☐		10	A1
10	I6-534006I1\I6-1263.wiff	214-10	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	3.08e+007	6.00	Base To Base	☐		10	A1
11	I6-534006I1\I6-1264.wiff	213-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	D1
12	I6-534006I1\I6-1265.wiff	220-1	Solvent Blank	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	E1
13	I6-534006I1\I6-1266.wiff	220-2	Blank Urine	Unknown			N/A	1.00	< 0	#BAD!	5.96e+004	6.11	Base To Base	☐		10	F1
14	I6-534006I1\I6-1267.wiff	220-3	Blank Urine	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	G1
15	I6-534006I1\I6-1268.wiff	220-4	Blank Urine	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	H1
16	I6-534006I1\I6-1269.wiff	213-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	G2
17	I6-534006I1\I6-1270.wiff	216-1	C 10	Standard		☒	10.000	1.00	10.583	5.8	3.23e+005	6.14	Base To Base	☐		10	C3
18	I6-534006I1\I6-1271.wiff	216-4	C 30	Standard		☒	30.000	1.00	28.465	-5.1	6.93e+005	6.09	Base To Base	☐		10	F3
19	I6-534006I1\I6-1272.wiff	216-7	C 100	Standard		☒	100.00	1.00	100.87	0.87	2.16e+006	6.14	Valley	☐		10	H3
20	I6-534006I1\I6-1273.wiff	216-10	C 300	Standard		☒	300.00	1.00	321.35	7.1	6.33e+006	6.16	Base To Base	☒	peak splitting factor	10	C4
21	I6-534006I1\I6-1274.wiff	216-13	C 500	Standard		☒	500.00	1.00	510.66	2.1	9.55e+006	6.12	Base To Base	☐		10	C4
22	I6-534006I1\I6-1275.wiff	216-16	C 750	Standard		☒	750.00	1.00	731.66	-2.4	1.29e+007	6.16	Base To Base	☐		10	C4
23	I6-534006I1\I6-1276.wiff	216-19	C 1000	Standard		☒	1000.0	1.00	1132.4	13.	1.77e+007	6.02	Base To Base	☐		10	F4
24	I6-534006I1\I6-1277.wiff	213-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	C6
25	I6-534006I1\I6-1278.wiff	217-1	QC 30	Quality Control		☒	30.000	1.00	27.867	-7.1	6.81e+005	6.11	Base To Base	☐		10	E6
26	I6-534006I1\I6-1279.wiff	217-4	QC 250	Quality Control		☒	250.00	1.00	226.99	-9.2	4.60e+006	6.09	Base To Base	☐		10	G6
27	I6-534006I1\I6-1280.wiff	217-7	QC 750	Quality Control		☒	750.00	1.00	769.59	2.6	1.34e+007	6.09	Base To Base	☐		10	D7
28	I6-534006I1\I6-1281.wiff	217-10	QC 30000	Quality Control		☒	30000.	1000.	28222.	-5.9	6.88e+005	6.15	Base To Base	☐		10	A7
29	I6-534006I1\I6-1282.wiff	213-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	D1
30	I6-534006I1\I6-1283.wiff	219-1	QC 30	Quality Control		☒	30.000	1.00	31.175	3.9	7.49e+005	6.10	Base To Base	☐		10	E6
31	I6-534006I1\I6-1284.wiff	219-4	QC 250	Quality Control		☒	250.00	1.00	240.16	-3.9	4.85e+006	6.04	Base To Base	☐		10	G6
32	I6-534006I1\I6-1285.wiff	219-7	QC 750	Quality Control		☒	750.00	1.00	750.46	0.062	1.31e+007	6.00	Valley	☐		10	D7
33	I6-534006I1\I6-1286.wiff	219-10	QC 30000	Quality Control		☒	30000.	1000.	27523.	-8.3	6.74e+005	6.03	Base To Base	☐		10	A7
34	I6-534006I1\I6-1287.wiff	213-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	D1
35	I6-534006I1\I6-1288.wiff	221-1	46664, 0-6 hr	Unknown			N/A	1000.	345340.	N/A	6.76e+006	6.09	Base To Base	☐		10	D1
36	I6-534006I1\I6-1289.wiff	221-2	46664, 0-6 hr rinse	Unknown			N/A	1000.	6510.1	N/A	2.38e+005	6.10	Base To Base	☐		10	D1
37	I6-534006I1\I6-1290.wiff	221-3	46667, 0-6 hr rinse	Unknown			N/A	1000.	96774.	N/A	2.08e+006	6.09	Base To Base	☐		10	D1
38	I6-534006I1\I6-1291.wiff	221-4	46670, 0-6 hr	Unknown			N/A	1000.	394510.	N/A	7.61e+006	6.09	Base To Base	☐		10	D1
39	I6-534006I1\I6-1292.wiff	221-5	46682, 0-6 hr	Unknown			N/A	1000.	564250.	N/A	1.04e+007	6.24	Base To Base	☐		10	D1
40	I6-534006I1\I6-1293.wiff	221-6	46683, 0-6 hr	Unknown			N/A	1000.	1394900.	N/A	2.01e+007	6.17	Valley	☐		10	D1
41	I6-534006I1\I6-1294.wiff	221-7	46683, 0-6 hr rinse	Unknown			N/A	1000.	12178.	N/A	3.56e+005	6.15	Base To Base	☐		10	D1
42	I6-534006I1\I6-1295.wiff	221-8	46690, 0-6 hr	Unknown			N/A	1000.	394380.	N/A	7.61e+006	6.14	Base To Base	☐		10	D1
43	I6-534006I1\I6-1296.wiff	221-9	46664, 6-12 hr	Unknown			N/A	1000.	141640.	N/A	2.97e+006	6.16	Base To Base	☐		10	D1
44	I6-534006I1\I6-1297.wiff	221-10	46667, 6-12 hr	Unknown			N/A	1000.	104600.	N/A	2.24e+006	6.22	Base To Base	☐		10	D1
45	I6-534006I1\I6-1298.wiff	221-11	46670, 6-12 hr	Unknown			N/A	1000.	89395.	N/A	1.93e+006	6.17	Base To Base	☐		10	D1
46	I6-534006I1\I6-1299.wiff	221-12	46682, 6-12 hr	Unknown			N/A	1000.	6970.5	N/A	2.48e+005	6.12	Base To Base	☐		10	D1
47	I6-534006I1\I6-1300.wiff	221-13	46683, 6-12 hr	Unknown			N/A	1000.	74686.	N/A	1.64e+006	6.04	Base To Base	☐		10	D1
48	I6-534006I1\I6-1301.wiff	221-14	46690, 6-12 hr	Unknown			N/A	1000.	113540.	N/A	2.41e+006	6.17	Base To Base	☐		10	D1
49	I6-534006I1\I6-1302.wiff	221-15	46664, 12-24 hr	Unknown			N/A	1000.	8081.7	N/A	2.71e+005	6.11	Base To Base	☐		10	D1
50	I6-534006I1\I6-1303.wiff	221-16	46667, 12-24 hr	Unknown			N/A	1000.	15157.	N/A	4.18e+005	6.20	Base To Base	☐		10	D1
51	I6-534006I1\I6-1304.wiff	221-17	46670, 12-24 hr	Unknown			N/A	1000.	8781.7	N/A	2.85e+005	6.22	Base To Base	☐		10	D1
52	I6-534006I1\I6-1305.wiff	213-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	D1
53	I6-534006I1\I6-1306.wiff	216-2	C 10	Standard		☒	10.000	1.00	11.390	14.	3.40e+005	6.23	Base To Base	☐		10	E3
54	I6-534006I1\I6-1307.wiff	216-5	C 30	Standard		☒	30.000	1.00	29.241	-2.5	7.09e+005	6.22	Base To Base	☐		10	F3
55	I6-534006I1\I6-1308.wiff	216-8	C 100	Standard		☒	100.00	1.00	103.14	3.1	2.21e+006	6.26	Base To Base	☐		10	B4
56	I6-534006I1\I6-1309.wiff	216-11	C 300	Standard		☒	300.00	1.00	306.71	2.2	6.07e+006	6.22	Base To Base	☐		10	E4
57	I6-534006I1\I6-1310.wiff	216-14	C 500	Standard		☒	500.00	1.00	472.40	-5.5	8.93e+006	6.17	Base To Base	☐		10	E4
58	I6-534006I1\I6-1311.wiff	216-17	C 750	Standard		☒	750.00	1.00	753.49	0.46	1.32e+007	6.15	Base To Base	☐		10	E4
59	I6-534006I1\I6-1312.wiff	216-20	C 1000	Standard		☒	1000.0	1.00	1014.0	1.4	1.65e+007	6.18	Valley	☐		10	G4
60	I6-534006I1\I6-1313.wiff	213-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	C6
61	I6-534006I1\I6-1314.wiff	217-2	QC 30	Quality Control		☒	30.000	1.00	26.876	-10.	6.60e+005	6.23	Base To Base	☐		10	E6
62	I6-534006I1\I6-1315.wiff	217-5	QC 250	Quality Control		☒	250.00	1.00	207.90	-17.	4.24e+006	6.23	Base To Base	☐		10	G6
63	I6-534006I1\I6-1316.wiff	217-8	QC 750	Quality Control		☒	750.00	1.00	758.41	1.1	1.32e+007	6.22	Base To Base	☐		10	D7
64	I6-534006I1\I6-1317.wiff	217-11	QC 30000	Quality Control		☒	30000.	1000.	25817.	-14.	6.39e+005	6.22	Base To Base	☒	peak splitting factor	10	A7
65	I6-534006I1\I6-1318.wiff	213-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	D1
66	I6-534006I1\I6-1319.wiff	219-2	QC 30	Quality Control		☒	30.000	1.00	29.406	-2.0	7.13e+005	6.15	Base To Base	☐		10	E6

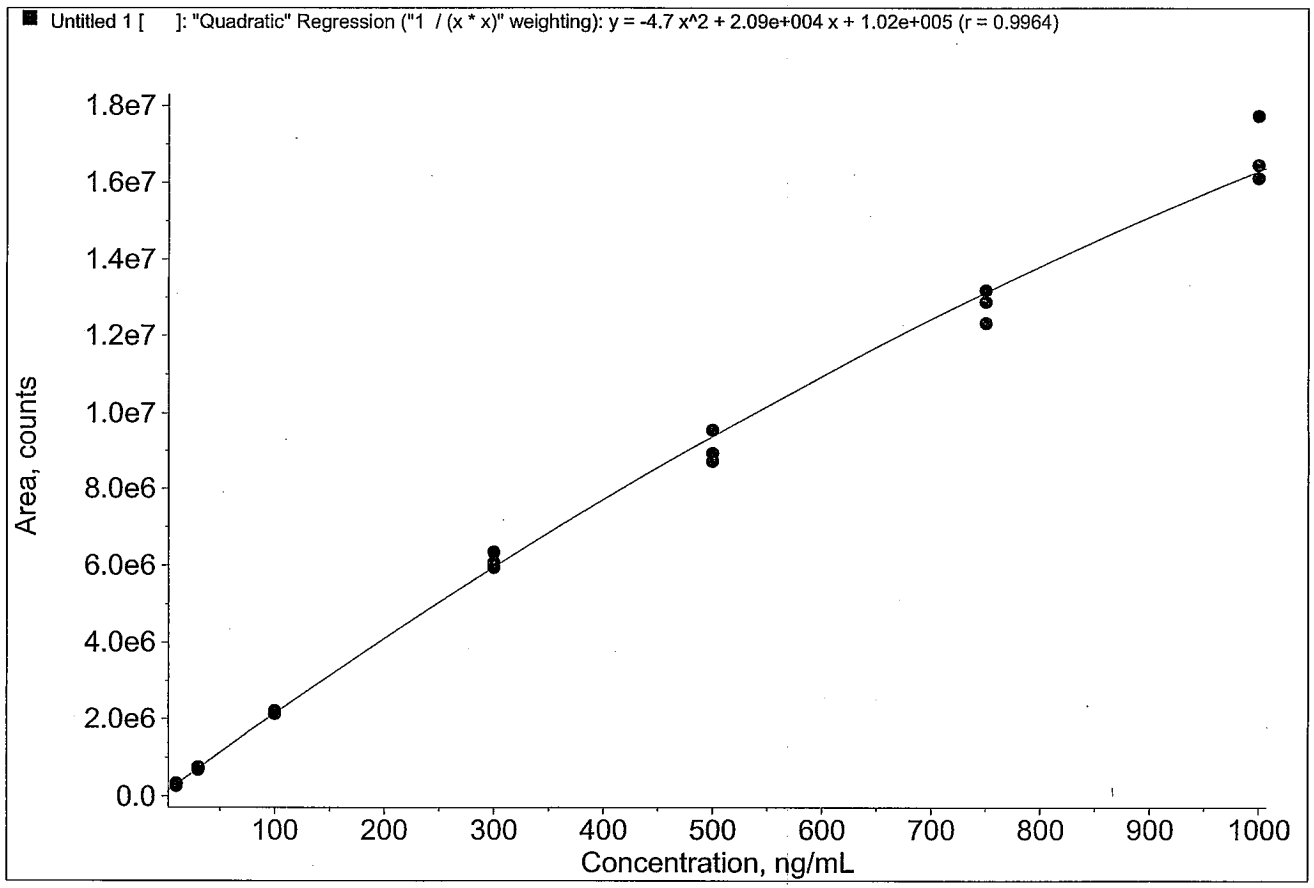
Results Path: \\Lcmsp03\sciexdata\Projects\534006\Bio\Results\I6-534006I1.rdb

	File Name	Sample ID	Sample Name	Sample Type	Analyte Peak Name	Use Record	Analyte Concentration (ng/mL)	Dilution Factor	Calculated Concentration (ng/mL)	%RE	Analyte Peak Area (counts)	Analyte Retention Time (min)	Analyte Integration Type	Record Modified	Sample Annotation	LCARTRIDGETRAY	LCARTRIDGEPOSITION
67	I6-534006I1\I6-1320.wiff	219-5	QC 250	Quality Control		☒	250.00	1.00	232.17	-7.1	4.70e+006	6.09	Base To Base	☐		10	G8
68	I6-534006I1\I6-1321.wiff	219-8	QC 750	Quality Control		☒	750.00	1.00	783.18	4.4	1.36e+007	6.14	Base To Base	☐		10	D7
69	I6-534006I1\I6-1322.wiff	219-11	QC 30000	Quality Control		☒	30000.	1000.	28519.	-4.9	6.94e+005	6.07	Base To Base	☐		10	A7
70	I6-534006I1\I6-1323.wiff	213-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	D1
71	I6-534006I1\I6-1324.wiff	222-1	46670, 0-6 hr rinse	Unknown			N/A	100.	4827.7	N/A	1.10e+006	6.21	Base To Base	☐		10	D1
72	I6-534006I1\I6-1325.wiff	222-2	46682, 0-6 hr rinse	Unknown			N/A	100.	8214.3	N/A	1.79e+006	6.17	Base To Base	☐		10	D1
73	I6-534006I1\I6-1326.wiff	222-3	46690, 0-6 hr rinse	Unknown			N/A	100.	7204.7	N/A	1.58e+006	6.24	Base To Base	☐		10	D1
74	I6-534006I1\I6-1327.wiff	222-4	46664, 6-12 hr rinse	Unknown			N/A	100.	3514.2	N/A	8.51e+005	6.20	Base To Base	☐		10	D1
75	I6-534006I1\I6-1328.wiff	222-5	46667, 6-12 hr rinse	Unknown			N/A	100.	1849.0	N/A	4.87e+005	6.22	Base To Base	☐		10	D1
76	I6-534006I1\I6-1329.wiff	222-6	46670, 6-12 hr rinse	Unknown			N/A	100.	2294.6	N/A	5.79e+005	6.09	Base To Base	☐		10	D1
77	I6-534006I1\I6-1330.wiff	222-7	46683, 6-12 hr rinse	Unknown			N/A	100.	2117.5	N/A	5.43e+005	6.22	Base To Base	☐		10	D1
78	I6-534006I1\I6-1331.wiff	222-8	46690, 6-12 hr rinse	Unknown			N/A	100.	2037.8	N/A	5.26e+005	6.25	Base To Base	☐		10	D1
79	I6-534006I1\I6-1332.wiff	222-9	46667, 12-24 hr rinse	Unknown			N/A	100.	948.30	N/A	3.00e+005	6.23	Base To Base	☐		10	D1
80	I6-534006I1\I6-1333.wiff	222-10	46682, 12-24 hr	Unknown			N/A	100.	669.74	N/A	2.42e+005	6.20	Base To Base	☐		10	D1
81	I6-534006I1\I6-1334.wiff	222-11	46683, 12-24 hr	Unknown			N/A	100.	767.00	N/A	2.62e+005	6.20	Base To Base	☐		10	D1
82	I6-534006I1\I6-1335.wiff	213-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	C6
83	I6-534006I1\I6-1336.wiff	217-3	QC 30	Quality Control		☒	30.000	1.00	24.937	-17.	6.20e+005	6.28	Base To Base	☐		10	E6
84	I6-534006I1\I6-1337.wiff	217-6	QC 250	Quality Control		☒	250.00	1.00	228.59	-8.6	4.63e+006	6.30	Base To Base	☐		10	G6
85	I6-534006I1\I6-1338.wiff	217-9	QC 750	Quality Control		☒	750.00	1.00	745.96	-0.54	1.31e+007	6.27	Base To Base	☐		10	D7
86	I6-534006I1\I6-1339.wiff	217-12	QC 30000	Quality Control		☒	30000.	1000.	26170.	-13.	6.46e+005	6.24	Base To Base	☐		10	A7
87	I6-534006I1\I6-1340.wiff	213-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	D1
88	I6-534006I1\I6-1341.wiff	219-3	QC 30	Quality Control		☒	30.000	1.00	29.927	-0.24	7.23e+005	6.14	Base To Base	☐		10	E6
89	I6-534006I1\I6-1342.wiff	219-6	QC 250	Quality Control		☒	250.00	1.00	252.99	1.2	5.09e+006	6.12	Base To Base	☐		10	G6
90	I6-534006I1\I6-1343.wiff	219-9	QC 750	Quality Control		☒	750.00	1.00	783.15	4.4	1.36e+007	6.14	Base To Base	☐		10	D7
91	I6-534006I1\I6-1344.wiff	219-12	QC 30000	Quality Control		☒	30000.	1000.	27956.	-6.8	6.83e+005	6.10	Base To Base	☐		10	A7
92	I6-534006I1\I6-1345.wiff	213-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	D1
93	I6-534006I1\I6-1346.wiff	216-3	C 10	Standard		☒	10.000	1.00	8.0645	-19.	2.71e+005	6.28	Base To Base	☒	peak splitting factor	10	F3
94	I6-534006I1\I6-1347.wiff	216-6	C 30	Standard		☒	30.000	1.00	31.452	4.8	7.55e+005	6.21	Base To Base	☐		10	F3
95	I6-534006I1\I6-1348.wiff	216-9	C 100	Standard		☒	100.00	1.00	99.180	-0.82	2.13e+006	6.31	Base To Base	☐		10	B4
96	I6-534006I1\I6-1349.wiff	216-12	C 300	Standard		☒	300.00	1.00	299.54	-0.15	5.94e+006	6.21	Base To Base	☒	peak splitting factor	10	E4
97	I6-534006I1\I6-1350.wiff	216-15	C 500	Standard		☒	500.00	1.00	459.37	-8.1	8.71e+006	6.27	Base To Base	☐		10	E4
98	I6-534006I1\I6-1351.wiff	216-18	C 750	Standard		☒	750.00	1.00	692.61	-7.7	1.23e+007	6.27	Base To Base	☐		10	E4
99	I6-534006I1\I6-1352.wiff	216-21	C 1000	Standard		☒	1000.0	1.00	984.27	-1.6	1.61e+007	6.29	Base To Base	☐		10	G4
100	I6-534006I1\I6-1353.wiff	213-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		10	D1

Printing Date: Friday, March 30, 2007

Operator: Shelley Hollar

Results Path: \\Lcmsp03\sciexdata\Projects\534006\Bio\Results\I6-534006I1.r
Results Name: I6-534006I1.rdb



Printing Date: Friday, March 30, 2007
Printing Time: 8:07:23 AM

Operator: Shelley Hollar
nalyst Version: 1.4.2

Table A-13: I6-534006m Data

Note:
Experimental urine sample analysis
Freeze-thaw cycle, 14-day frozen and 4 hour benchtop stability assessments.
534006-227-4 was not included in the regression calculations based on the test for outliers.

Study Record Page: 237a

Results Path: \\Lcmsp03\sciexdata\Projects\534006\Bio\Results\I6-534006m.rd
Results Name: I6-534006m.rdb

	File Name	Sample ID	Sample Name	Sample Type	Analyte Peak Name	Use Record	Analyte Concentration (ng/mL)	Dilution Factor	Calculated Concentration (ng/mL)	%RE	Analyte Peak Area (counts)	Analyte Retention Time (min)	Analyte Integration Type	Record Modified	Sample Annotation
1	I6-534006m\I6-1354.wiff		Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	1.73e+007	6.09	Base To Base	☐	
2	I6-534006m\I6-1355.wiff		Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	1.68e+007	6.00	Base To Base	☐	
3	I6-534006m\I6-1356.wiff		Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	1.70e+007	5.97	Base To Base	☐	
4	I6-534006m\I6-1357.wiff		Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	1.72e+007	6.01	Base To Base	☐	
5	I6-534006m\I6-1358.wiff		Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	1.72e+007	5.96	Base To Base	☐	
6	I6-534006m\I6-1359.wiff		Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	1.75e+007	6.04	Base To Base	☐	
7	I6-534006m\I6-1360.wiff		Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	1.79e+007	5.95	Base To Base	☒	peak splitting factor
8	I6-534006m\I6-1361.wiff		Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	1.80e+007	5.95	Base To Base	☐	
9	I6-534006m\I6-1362.wiff		Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	1.76e+007	5.97	Base To Base	☐	
10	I6-534006m\I6-1363.wiff		Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	1.78e+007	5.93	Base To Base	☐	
11	I6-534006m\I6-1364.wiff	234-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
12	I6-534006m\I6-1365.wiff	229-1	Solvent Blank	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
13	I6-534006m\I6-1366.wiff	229-2	Blank Urine	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
14	I6-534006m\I6-1367.wiff	229-3	Blank Urine	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
15	I6-534006m\I6-1368.wiff	229-4	Blank Urine	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
16	I6-534006m\I6-1369.wiff	234-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
17	I6-534006m\I6-1370.wiff	227-1	C 10	Standard		☒	10.000	1.00	9.2867	-7.1	9.66e+004	5.82	Base To Base	☐	
18	I6-534006m\I6-1371.wiff	227-4	C 30	Standard		☐	30.000	1.00	67.890	130.	6.79e+005	5.77	Base To Base	☐	
19	I6-534006m\I6-1372.wiff	227-7	C 100	Standard		☒	100.00	1.00	87.750	-12.	8.74e+005	5.88	Base To Base	☐	
20	I6-534006m\I6-1373.wiff	227-10	C 300	Standard		☒	300.00	1.00	311.93	4.0	2.95e+006	5.90	Base To Base	☐	
21	I6-534006m\I6-1374.wiff	227-13	C 500	Standard		☒	500.00	1.00	516.33	3.3	4.65e+006	5.88	Base To Base	☐	
22	I6-534006m\I6-1375.wiff	227-16	C 750	Standard		☒	750.00	1.00	757.42	0.99	6.42e+006	5.88	Base To Base	☐	
23	I6-534006m\I6-1376.wiff	227-19	C 1000	Standard		☒	1000.0	1.00	918.88	-8.1	7.47e+006	5.86	Base To Base	☐	
24	I6-534006m\I6-1377.wiff	234-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
25	I6-534006m\I6-1378.wiff	228-1	QC 30	Quality Control		☒	30.000	1.00	28.834	-3.9	2.93e+005	5.91	Base To Base	☐	
26	I6-534006m\I6-1379.wiff	228-4	QC 250	Quality Control		☒	250.00	1.00	224.67	-10.	2.17e+006	5.90	Valley	☐	
27	I6-534006m\I6-1380.wiff	228-7	QC 750	Quality Control		☒	750.00	1.00	645.14	-14.	5.63e+006	5.78	Base To Base	☐	
28	I6-534006m\I6-1381.wiff	228-10	QC 150000	Quality Control		☒	150000.	5000.	173620.	16.	3.51e+005	5.82	Base To Base	☐	
29	I6-534006m\I6-1382.wiff	234-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
30	I6-534006m\I6-1383.wiff	230-1	46683, 0-6 hr	Unknown			N/A	5000.	1533800.	N/A	2.90e+006	5.87	Base To Base	☐	
31	I6-534006m\I6-1384.wiff	234-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
32	I6-534006m\I6-1385.wiff	231-1	46664, 0-6 hr rinse	Unknown			N/A	200.	10363.	N/A	5.21e+005	5.85	Base To Base	☐	
33	I6-534006m\I6-1386.wiff	231-2	46682, 6-12 hr	Unknown			N/A	200.	683.33	N/A	3.74e+004	5.74	Base To Base	☐	
34	I6-534006m\I6-1387.wiff	234-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
35	I6-534006m\I6-1388.wiff	232-1	46682, 12-24 hr	Unknown			N/A	2.00	No Intercept	#BAD!	4.09e+007	5.89	Base To Base	☐	
36	I6-534006m\I6-1389.wiff	232-2	46683, 12-24 hr	Unknown			N/A	2.00	1315.4	N/A	5.72e+006	5.92	Base To Base	☐	
37	I6-534006m\I6-1390.wiff	234-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
38	I6-534006m\I6-1391.wiff	233-1	30 ng/mL 4 Hr Rt Slb	Unknown			N/A	1.00	31.238	N/A	3.17e+005	5.96	Base To Base	☐	
39	I6-534006m\I6-1392.wiff	233-2	30 ng/mL 4 Hr Rt Slb	Unknown			N/A	1.00	28.626	N/A	2.91e+005	5.89	Base To Base	☐	
40	I6-534006m\I6-1393.wiff	233-3	30 ng/mL 4 Hr Rt Slb	Unknown			N/A	1.00	28.302	N/A	2.87e+005	5.93	Base To Base	☐	
41	I6-534006m\I6-1394.wiff	233-4	750 ng/mL 4 Hr Rt Slb	Unknown			N/A	1.00	761.39	N/A	6.45e+006	5.88	Base To Base	☒	peak splitting factor
42	I6-534006m\I6-1395.wiff	233-5	750 ng/mL 4 Hr Rt Slb	Unknown			N/A	1.00	765.74	N/A	6.48e+006	5.91	Base To Base	☐	
43	I6-534006m\I6-1396.wiff	233-6	750 ng/mL 4 Hr Rt Slb	Unknown			N/A	1.00	826.46	N/A	6.88e+006	5.89	Base To Base	☐	
44	I6-534006m\I6-1397.wiff	234-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
45	I6-534006m\I6-1398.wiff	227-2	C 10	Standard		☒	10.000	1.00	9.5620	-4.4	9.94e+004	5.88	Base To Base	☐	
46	I6-534006m\I6-1399.wiff	227-5	C 30	Standard		☒	30.000	1.00	28.830	-3.9	2.93e+005	6.00	Base To Base	☐	
47	I6-534006m\I6-1400.wiff	227-8	C 100	Standard		☒	100.00	1.00	105.56	5.6	1.05e+006	5.82	Base To Base	☐	
48	I6-534006m\I6-1401.wiff	227-11	C 300	Standard		☒	300.00	1.00	294.75	-1.8	2.80e+006	5.88	Base To Base	☐	
49	I6-534006m\I6-1402.wiff	227-14	C 500	Standard		☒	500.00	1.00	535.69	7.1	4.80e+006	5.86	Valley	☐	
50	I6-534006m\I6-1403.wiff	227-17	C 750	Standard		☒	750.00	1.00	672.67	-10.	5.83e+006	5.84	Valley	☐	
51	I6-534006m\I6-1404.wiff	227-20	C 1000	Standard		☒	1000.0	1.00	1080.6	8.1	8.40e+006	5.90	Base To Base	☐	
52	I6-534006m\I6-1405.wiff	234-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
53	I6-534006m\I6-1406.wiff	228-2	QC 30	Quality Control		☒	30.000	1.00	28.265	-5.8	2.87e+005	5.89	Base To Base	☐	

Printing Date: Wednesday, April 04, 2007
Printing Time: 8:26:26 AM

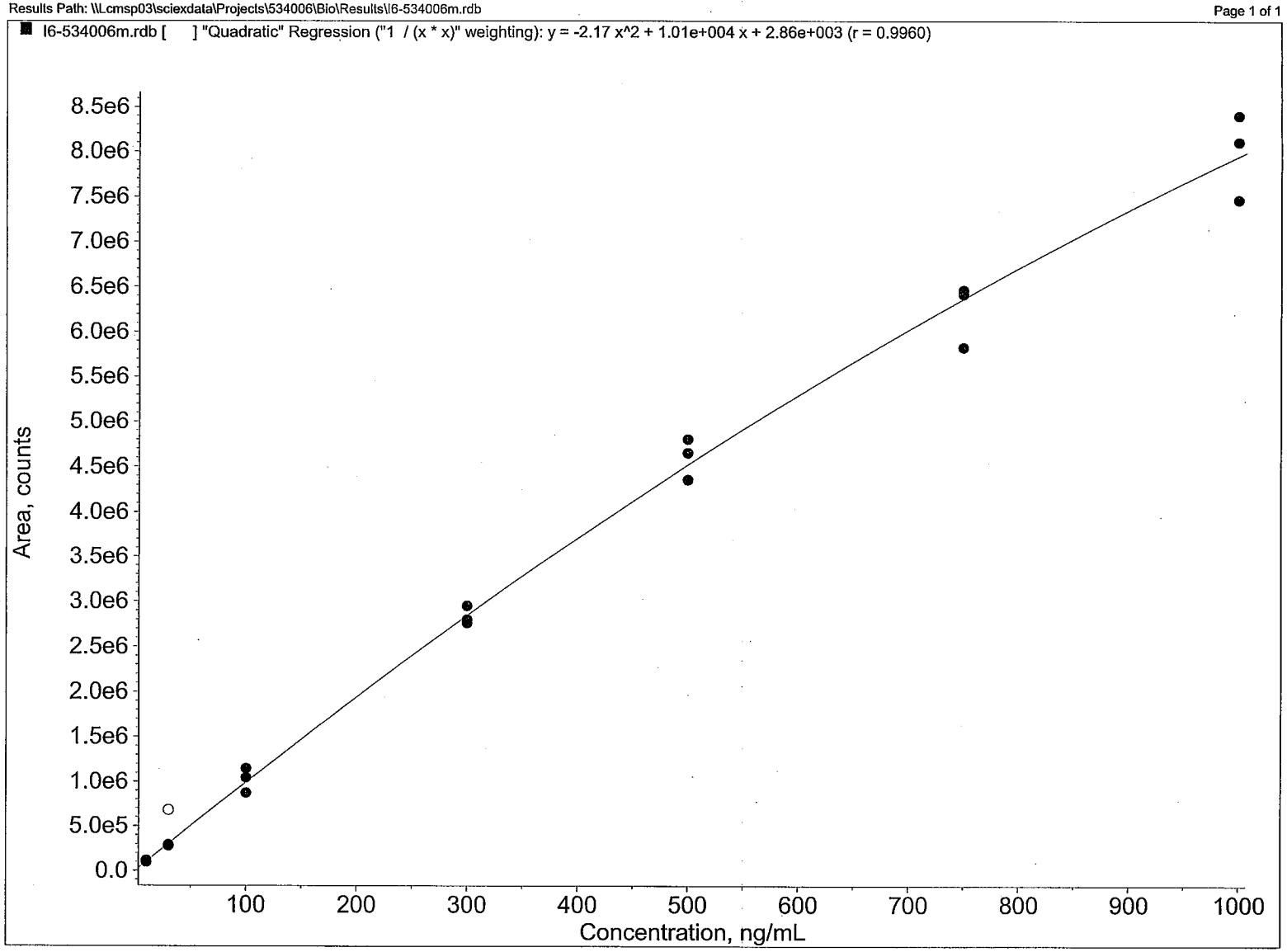
Operator: Shelley Hollar
nalyst Version: 1.4.2

Results Path: \\Lcmsp03\sciexdata\Projects\534006\Bio\Results\I6-534006m.rd
Results Name: I6-534006m.rdb

	File Name	Sample ID	Sample Name	Sample Type	Analyte Peak Name	Use Record	Analyte Concentration (ng/mL)	Dilution Factor	Calculated Concentration (ng/mL)	%RE	Analyte Peak Area (counts)	Analyte Retention Time (min)	Analyte Integration Type	Record Modified	Sample Annotation
54	I6-534006m\I6-1407.wiff	228-5	QC 250	Quality Control		☒	250.00	1.00	207.20	-17.	2.01e+006	5.89	Base To Base	☐	
55	I6-534006m\I6-1408.wiff	228-8	QC 750	Quality Control		☒	750.00	1.00	683.29	-8.9	5.90e+006	5.87	Base To Base	☐	
56	I6-534006m\I6-1409.wiff	228-11	QC 150000	Quality Control		☒	150000.	5000.	164740.	9.8	3.34e+005	5.86	Base To Base	☒	peak splitting factor
57	I6-534006m\I6-1410.wiff	234-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
58	I6-534006m\I6-1411.wiff	235-1	30 ng/mL F Thaw	Unknown			N/A	1.00	31.558	N/A	3.20e+005	5.92	Base To Base	☐	
59	I6-534006m\I6-1412.wiff	235-2	30 ng/mL F Thaw	Unknown			N/A	1.00	30.036	N/A	3.05e+005	5.89	Base To Base	☐	
60	I6-534006m\I6-1413.wiff	235-3	30 ng/mL F Thaw	Unknown			N/A	1.00	29.277	N/A	2.97e+005	6.00	Base To Base	☐	
61	I6-534006m\I6-1414.wiff	235-4	30 ng/mL F Thaw	Unknown			N/A	1.00	31.244	N/A	3.17e+005	5.94	Base To Base	☐	
62	I6-534006m\I6-1415.wiff	235-5	30 ng/mL F Thaw	Unknown			N/A	1.00	28.084	N/A	2.85e+005	5.98	Base To Base	☐	
63	I6-534006m\I6-1416.wiff	235-6	30 ng/mL F Thaw	Unknown			N/A	1.00	29.979	N/A	3.04e+005	5.95	Base To Base	☐	
64	I6-534006m\I6-1417.wiff	235-7	30 ng/mL F Thaw	Unknown			N/A	1.00	30.692	N/A	3.11e+005	5.90	Base To Base	☐	
65	I6-534006m\I6-1418.wiff	235-8	30 ng/mL F Thaw	Unknown			N/A	1.00	28.488	N/A	2.89e+005	5.99	Base To Base	☐	
66	I6-534006m\I6-1419.wiff	235-9	30 ng/mL F Thaw	Unknown			N/A	1.00	29.403	N/A	2.98e+005	5.95	Base To Base	☐	
67	I6-534006m\I6-1420.wiff	235-10	750 ng/mL F Thaw	Unknown			N/A	1.00	808.71	N/A	6.77e+006	5.96	Base To Base	☐	
68	I6-534006m\I6-1421.wiff	235-11	750 ng/mL F Thaw	Unknown			N/A	1.00	878.47	N/A	7.22e+006	5.95	Base To Base	☐	
69	I6-534006m\I6-1422.wiff	235-12	750 ng/mL F Thaw	Unknown			N/A	1.00	830.72	N/A	6.91e+006	5.99	Base To Base	☐	
70	I6-534006m\I6-1423.wiff	235-13	750 ng/mL F Thaw	Unknown			N/A	1.00	861.41	N/A	7.11e+006	5.95	Base To Base	☐	
71	I6-534006m\I6-1424.wiff	235-14	750 ng/mL F Thaw	Unknown			N/A	1.00	899.14	N/A	7.35e+006	5.95	Base To Base	☐	
72	I6-534006m\I6-1425.wiff	235-15	750 ng/mL F Thaw	Unknown			N/A	1.00	668.23	N/A	5.79e+006	5.86	Base To Base	☐	
73	I6-534006m\I6-1426.wiff	235-16	750 ng/mL F Thaw	Unknown			N/A	1.00	822.95	N/A	6.86e+006	5.95	Base To Base	☐	
74	I6-534006m\I6-1427.wiff	235-17	750 ng/mL F Thaw	Unknown			N/A	1.00	759.15	N/A	6.43e+006	5.88	Base To Base	☐	
75	I6-534006m\I6-1428.wiff	235-18	750 ng/mL F Thaw	Unknown			N/A	1.00	870.17	N/A	7.16e+006	5.97	Base To Base	☐	
76	I6-534006m\I6-1429.wiff	234-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
77	I6-534006m\I6-1430.wiff	228-3	QC 30	Quality Control		☒	30.000	1.00	27.496	-8.3	2.79e+005	5.92	Base To Base	☐	
78	I6-534006m\I6-1431.wiff	228-6	QC 250	Quality Control		☒	250.00	1.00	265.19	6.1	2.53e+006	5.85	Base To Base	☐	
79	I6-534006m\I6-1432.wiff	228-9	QC 750	Quality Control		☒	750.00	1.00	818.12	9.1	6.83e+006	5.85	Base To Base	☐	
80	I6-534006m\I6-1433.wiff	228-12	QC 150000	Quality Control		☒	150000.	5000.	160180.	6.8	3.25e+005	5.89	Base To Base	☒	peak splitting factor
81	I6-534006m\I6-1434.wiff	234-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
82	I6-534006m\I6-1435.wiff	227-3	C 10	Standard		☒	10.000	1.00	11.459	15.	1.18e+005	5.91	Valley	☐	
83	I6-534006m\I6-1436.wiff	227-6	C 30	Standard		☒	30.000	1.00	27.572	-8.1	2.80e+005	5.87	Base To Base	☐	
84	I6-534006m\I6-1437.wiff	227-9	C 100	Standard		☒	100.00	1.00	116.01	16.	1.15e+006	5.94	Base To Base	☐	
85	I6-534006m\I6-1438.wiff	227-12	C 300	Standard		☒	300.00	1.00	290.51	-3.2	2.76e+006	5.94	Base To Base	☐	
86	I6-534006m\I6-1439.wiff	227-15	C 500	Standard		☒	500.00	1.00	479.39	-4.1	4.35e+006	5.91	Base To Base	☐	
87	I6-534006m\I6-1440.wiff	227-18	C 750	Standard		☒	750.00	1.00	763.54	1.8	6.46e+006	5.94	Base To Base	☐	
88	I6-534006m\I6-1441.wiff	227-21	C 1000	Standard		☒	1000.0	1.00	1027.2	2.7	8.11e+006	6.00	Base To Base	☐	
89	I6-534006m\I6-1442.wiff	234-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	

Printing Date: Wednesday, April 04, 2007
Printing Time: 8:26:26 AM

Operator: Shelley Hollar
nalyst Version: 1.4.2


I6-534006m.rdb [ ] "Quadratic" Regression ("1 / (x * x)" weighting): y = -2.17 x^2 + 1.01e+004 x + 2.86e+003 (r = 0.9960)
Area, counts
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8.0e6
7.5e6
7.0e6
6.5e6
6.0e6
5.5e6
5.0e6
4.5e6
4.0e6
3.5e6
3.0e6
2.5e6
2.0e6
1.5e6
1.0e6
5.0e5
0.0
100
200
300
400
500
600
700
800
900
1000
Concentration, ng/mL

Table A-14: I6-534006o Data

Note:
Experimental urine sample analysis

Study Record Page: 256a

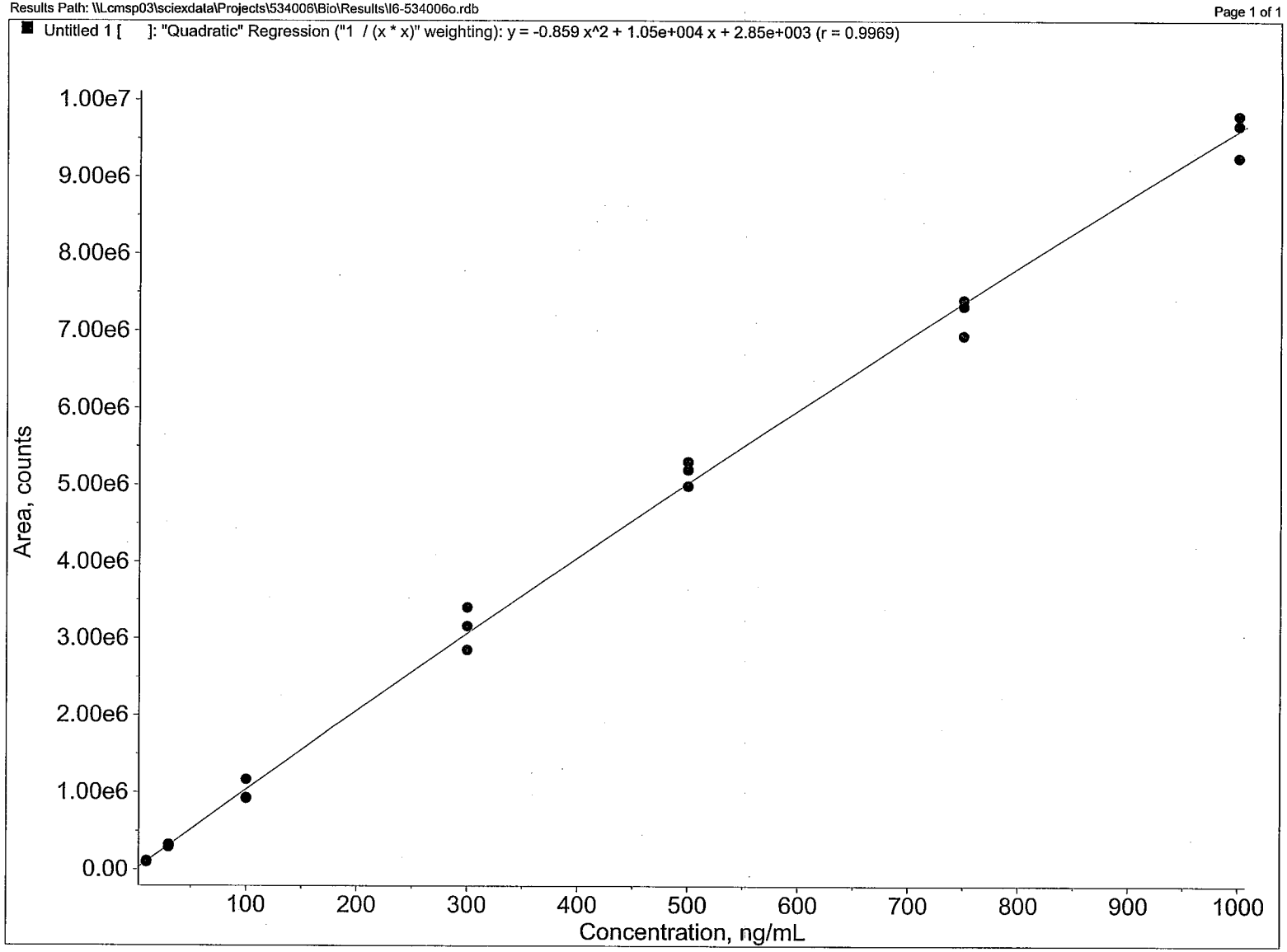
Results Path: \\Lcmsp03\sciexdata\Projects\534006\Bio\Results\I6-534006o.rdb

	File Name	Sample ID	Sample Name	Sample Type	Analyte Peak Name	Use Record	Analyte Concentration (ng/mL)	Dilution Factor	Calculated Concentration (ng/mL)	%RE	Analyte Peak Area (counts)	Analyte Retention Time (min)	Analyte Integration Type	Record Modified	Sample Annotation
1	I6-534006o\I6-1514.wiff	248-10	Test Solution	Unknown			N/A	1.00	1696.2	N/A	1.53e+007	5.78	Base To Base	☐	
2	I6-534006o\I6-1515.wiff	248-10	Test Solution	Unknown			N/A	1.00	1795.2	N/A	1.60e+007	5.83	Base To Base	☐	
3	I6-534006o\I6-1516.wiff	248-10	Test Solution	Unknown			N/A	1.00	1799.3	N/A	1.61e+007	5.69	Base To Base	☐	
4	I6-534006o\I6-1517.wiff	248-10	Test Solution	Unknown			N/A	1.00	1872.9	N/A	1.66e+007	5.74	Base To Base	☐	
5	I6-534006o\I6-1518.wiff	248-10	Test Solution	Unknown			N/A	1.00	1844.3	N/A	1.64e+007	5.75	Base To Base	☐	
6	I6-534006o\I6-1519.wiff	248-10	Test Solution	Unknown			N/A	1.00	1934.7	N/A	1.70e+007	5.76	Base To Base	☐	
7	I6-534006o\I6-1520.wiff	248-10	Test Solution	Unknown			N/A	1.00	1956.5	N/A	1.72e+007	5.72	Base To Base	☐	
8	I6-534006o\I6-1521.wiff	248-10	Test Solution	Unknown			N/A	1.00	1947.1	N/A	1.71e+007	5.72	Base To Base	☐	
9	I6-534006o\I6-1522.wiff	248-10	Test Solution	Unknown			N/A	1.00	2016.4	N/A	1.76e+007	5.68	Base To Base	☐	
10	I6-534006o\I6-1523.wiff	248-10	Test Solution	Unknown			N/A	1.00	2169.6	N/A	1.87e+007	5.68	Base To Base	☐	
11	I6-534006o\I6-1524.wiff	256-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
12	I6-534006o\I6-1525.wiff	252-1	Solvent Blank	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
13	I6-534006o\I6-1526.wiff	252-2	Blank Urine	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
14	I6-534006o\I6-1527.wiff	252-3	Blank Urine	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
15	I6-534006o\I6-1528.wiff	252-4	Blank Urine	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
16	I6-534006o\I6-1529.wiff	256-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
17	I6-534006o\I6-1530.wiff	250-1	C 10	Standard		☒	10.000	1.00	9.1005	-9.0	9.80e+004	5.54	Base To Base	☒	noise % peak splitting
18	I6-534006o\I6-1531.wiff	250-2	C 10	Standard		☒	10.000	1.00	10.345	3.5	1.11e+005	5.62	Base To Base	☒	noise % peak splitting
19	I6-534006o\I6-1532.wiff	250-4	C 30	Standard		☒	30.000	1.00	31.185	4.0	3.28e+005	5.62	Base To Base	☒	peak splitting ratio
20	I6-534006o\I6-1533.wiff	250-5	C 30	Standard		☒	30.000	1.00	27.949	-6.8	2.95e+005	5.60	Base To Base	☐	
21	I6-534006o\I6-1534.wiff	250-7	C 100	Standard		☒	100.00	1.00	89.411	-11.	9.32e+005	5.52	Base To Base	☐	
22	I6-534006o\I6-1535.wiff	250-8	C 100	Standard		☒	100.00	1.00	88.591	-11.	9.23e+005	5.54	Base To Base	☐	
23	I6-534006o\I6-1536.wiff	250-10	C 300	Standard		☒	300.00	1.00	278.52	-7.2	2.85e+006	5.60	Base To Base	☐	
24	I6-534006o\I6-1537.wiff	250-13	C 500	Standard		☒	500.00	1.00	496.08	-0.78	4.98e+006	5.58	Base To Base	☐	
25	I6-534006o\I6-1538.wiff	250-16	C 750	Standard		☒	750.00	1.00	703.34	-6.2	6.94e+006	5.52	Base To Base	☐	
26	I6-534006o\I6-1539.wiff	250-19	C 1000	Standard		☒	1000.0	1.00	959.94	-4.0	9.26e+006	5.53	Base To Base	☐	
27	I6-534006o\I6-1540.wiff	256-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
28	I6-534006o\I6-1541.wiff	251-1	QC 30	Quality Control		☒	30.000	1.00	30.061	0.20	3.17e+005	5.57	Base To Base	☐	
29	I6-534006o\I6-1542.wiff	251-2	QC 30	Quality Control		☒	30.000	1.00	26.901	-10.	2.84e+005	5.64	Base To Base	☒	peak splitting factor
30	I6-534006o\I6-1543.wiff	251-4	QC 250	Quality Control		☒	250.00	1.00	252.84	1.1	2.59e+006	5.55	Base To Base	☐	
31	I6-534006o\I6-1544.wiff	251-5	QC 250	Quality Control		☒	250.00	1.00	258.15	3.3	2.65e+006	5.54	Base To Base	☐	
32	I6-534006o\I6-1545.wiff	251-7	QC 750	Quality Control		☒	750.00	1.00	807.06	7.6	7.89e+006	5.55	Base To Base	☐	
33	I6-534006o\I6-1546.wiff	251-10	QC 30000	Quality Control		☒	30000.	100.	29442.	-1.9	3.01e+006	5.51	Base To Base	☐	
34	I6-534006o\I6-1547.wiff	256-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
35	I6-534006o\I6-1548.wiff	253-1	46682, 6-12 hr	Unknown			N/A	100.	12069.	N/A	1.25e+006	5.52	Base To Base	☐	
36	I6-534006o\I6-1549.wiff	254-1	46682, 12-24 hr	Unknown			N/A	50.0	1200.3	N/A	2.54e+005	5.45	Base To Base	☐	
37	I6-534006o\I6-1550.wiff	256-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
38	I6-534006o\I6-1551.wiff	251-3	QC 30	Quality Control		☒	30.000	1.00	27.302	-9.0	2.88e+005	5.53	Base To Base	☐	
39	I6-534006o\I6-1552.wiff	251-6	QC 250	Quality Control		☒	250.00	1.00	224.11	-10.	2.30e+006	5.53	Base To Base	☐	
40	I6-534006o\I6-1553.wiff	251-8	QC 750	Quality Control		☒	750.00	1.00	735.91	-1.9	7.24e+006	5.61	Base To Base	☐	
41	I6-534006o\I6-1554.wiff	251-9	QC 750	Quality Control		☒	750.00	1.00	731.69	-2.4	7.20e+006	5.60	Base To Base	☐	
42	I6-534006o\I6-1555.wiff	251-11	QC 30000	Quality Control		☒	30000.	100.	28811.	-4.0	2.95e+006	5.54	Base To Base	☐	
43	I6-534006o\I6-1556.wiff	251-12	QC 30000	Quality Control		☒	30000.	100.	32312.	7.7	3.29e+006	5.47	Base To Base	☐	
44	I6-534006o\I6-1557.wiff	256-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
45	I6-534006o\I6-1558.wiff	250-3	C 10	Standard		☒	10.000	1.00	10.604	6.0	1.14e+005	5.57	Base To Base	☐	
46	I6-534006o\I6-1559.wiff	250-6	C 30	Standard		☒	30.000	1.00	30.970	3.2	3.26e+005	5.58	Base To Base	☐	
47	I6-534006o\I6-1560.wiff	250-9	C 100	Standard		☒	100.00	1.00	112.69	13.	1.17e+006	5.59	Base To Base	☐	
48	I6-534006o\I6-1561.wiff	250-11	C 300	Standard		☒	300.00	1.00	334.20	11.	3.40e+006	5.55	Base To Base	☐	
49	I6-534006o\I6-1562.wiff	250-12	C 300	Standard		☒	300.00	1.00	309.52	3.2	3.16e+006	5.53	Base To Base	☐	
50	I6-534006o\I6-1563.wiff	250-14	C 500	Standard		☒	500.00	1.00	528.93	5.8	5.30e+006	5.55	Base To Base	☐	
51	I6-534006o\I6-1564.wiff	250-15	C 500	Standard		☒	500.00	1.00	518.22	3.6	5.20e+006	5.48	Base To Base	☐	
52	I6-534006o\I6-1565.wiff	250-17	C 750	Standard		☒	750.00	1.00	753.65	0.49	7.40e+006	5.55	Base To Base	☐	
53	I6-534006o\I6-1566.wiff	250-18	C 750	Standard		☒	750.00	1.00	744.89	-0.68	7.32e+006	5.55	Base To Base	☐	
54	I6-534006o\I6-1567.wiff	250-20	C 1000	Standard		☒	1000.0	1.00	1007.4	0.74	9.67e+006	5.50	Base To Base	☐	
55	I6-534006o\I6-1568.wiff	250-21	C 1000	Standard		☒	1000.0	1.00	1021.9	2.2	9.80e+006	5.62	Base To Base	☐	
56	I6-534006o\I6-1569.wiff	256-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	

Printing Date: Monday, April 09, 2007

Operator: Shelley Hollar

Results Path: \\Lcmsp03\sciexdata\Projects\534006\Bio\Results\l6-534006o.rdb



Printing Date: Monday, April 09, 2007

Operator: Shelley Hollar

Table A-15: I6-534006p1 Data

Note:

- Serum Long Term Stability
- Serum Freeze Thaw Stability

Study Record Page: 266b to 266c

Results Path: \\Lcmsp03\sciexdata\Projects\534006\Bio\Results\I6-534006p1.rdb

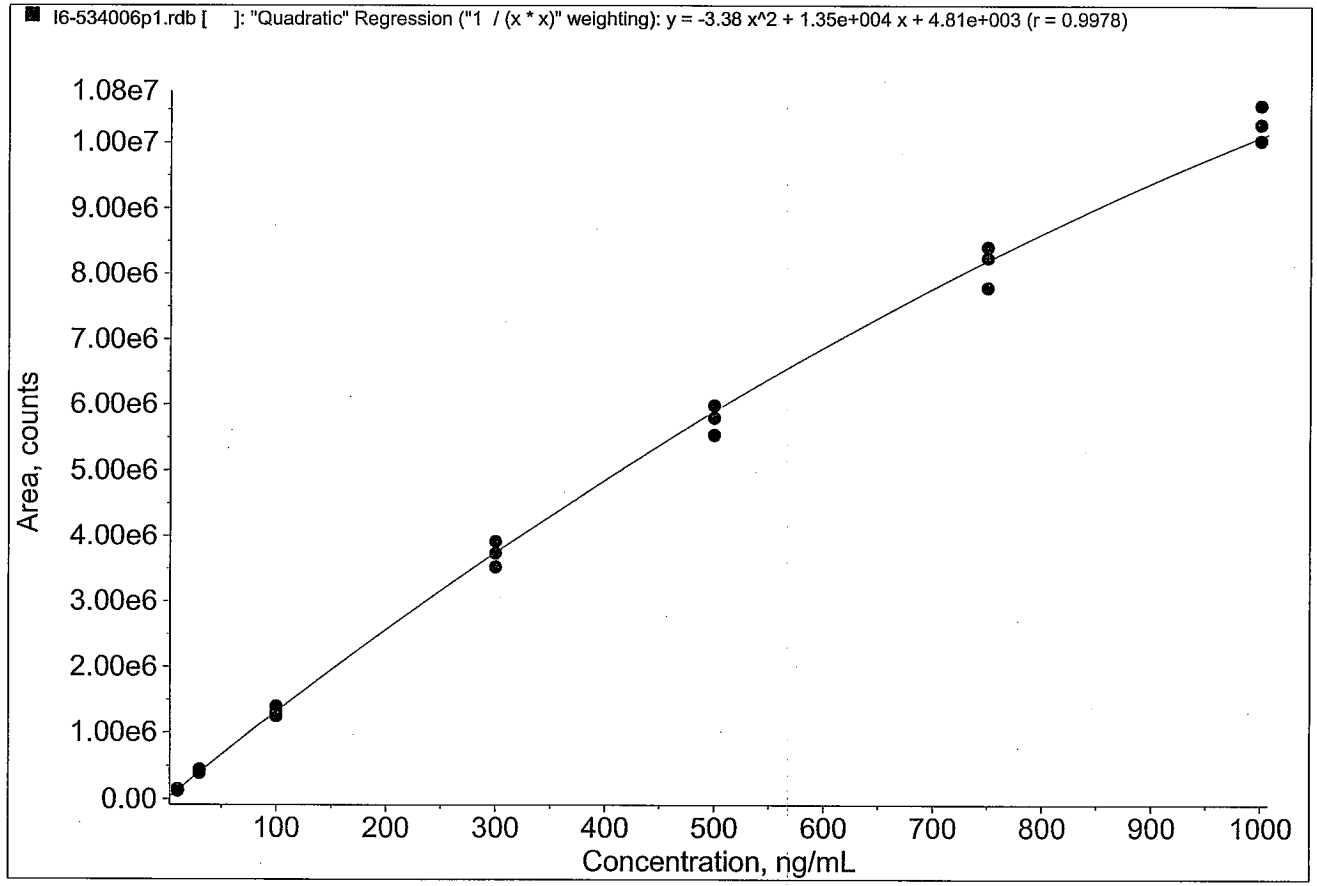
	File Name	Sample ID	Sample Name	Sample Type	Analyte Peak Name	Use Record	Analyte Concentration (ng/mL)	Dilution Factor	Calculated Concentration (ng/mL)	%RE	Analyte Peak Area (counts)	Analyte Retention Time (min)	Analyte Integration Type	Record Modified	Sample Annotation
1	I6-534006p\I6-1647.wiff	259-10	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	1.69e+007	4.66	Valley	☐	
2	I6-534006p\I6-1648.wiff	259-10	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	1.67e+007	4.63	Base To Base	☐	
3	I6-534006p\I6-1649.wiff	259-10	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	1.72e+007	4.66	Base To Base	☐	
4	I6-534006p\I6-1650.wiff	259-10	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	1.70e+007	4.63	Valley	☐	
5	I6-534006p\I6-1651.wiff	259-10	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	1.75e+007	4.66	Base To Base	☐	
6	I6-534006p\I6-1652.wiff	259-10	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	1.73e+007	4.70	Base To Base	☐	
7	I6-534006p\I6-1653.wiff	259-10	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	1.72e+007	4.69	Base To Base	☐	
8	I6-534006p\I6-1654.wiff	259-10	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	1.70e+007	4.72	Base To Base	☐	
9	I6-534006p\I6-1655.wiff	259-10	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	1.68e+007	4.67	Valley	☐	
10	I6-534006p\I6-1656.wiff	259-10	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	1.71e+007	4.71	Base To Base	☐	
11	I6-534006p\I6-1657.wiff	257-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
12	I6-534006p\I6-1658.wiff	263-1	Solvent Blank	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
13	I6-534006p\I6-1659.wiff	263-2	Blank Serum	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
14	I6-534006p\I6-1660.wiff	263-3	Blank Serum	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
15	I6-534006p\I6-1661.wiff	263-4	Blank Serum	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
16	I6-534006p\I6-1662.wiff	257-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
17	I6-534006p\I6-1663.wiff	261-1	C 10	Standard		☒	10.000	1.00	8.8149	-12.	1.23e+005	4.56	Valley	☐	
18	I6-534006p\I6-1664.wiff	261-4	C 30	Standard		☒	30.000	1.00	28.859	-3.8	3.91e+005	4.61	Base To Base	☐	
19	I6-534006p\I6-1665.wiff	261-7	C 100	Standard		☒	100.00	1.00	94.321	-5.7	1.25e+006	4.55	Base To Base	☐	
20	I6-534006p\I6-1666.wiff	261-10	C 300	Standard		☒	300.00	1.00	280.70	-6.4	3.52e+006	4.59	Base To Base	☐	
21	I6-534006p\I6-1667.wiff	261-13	C 500	Standard		☒	500.00	1.00	464.67	-7.1	5.54e+006	4.57	Base To Base	☒	Peak splitting factor
22	I6-534006p\I6-1668.wiff	261-16	C 750	Standard		☒	750.00	1.00	701.21	-6.5	7.79e+006	4.57	Base To Base	☐	
23	I6-534006p\I6-1669.wiff	261-19	C 1000	Standard		☒	1000.0	1.00	991.67	-0.83	1.00e+007	4.56	Base To Base	☐	
24	I6-534006p\I6-1670.wiff	257-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
25	I6-534006p\I6-1671.wiff	262-1	QC 30	Quality Control		☒	30.000	1.00	30.900	3.0	4.18e+005	4.56	Base To Base	☐	
26	I6-534006p\I6-1672.wiff	262-4	QC 250	Quality Control		☒	250.00	1.00	254.20	1.7	3.21e+006	4.54	Base To Base	☐	
27	I6-534006p\I6-1673.wiff	262-7	QC 750	Quality Control		☒	750.00	1.00	762.50	1.7	8.31e+006	4.50	Base To Base	☐	
28	I6-534006p\I6-1674.wiff	257-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
29	I6-534006p\I6-1675.wiff	264-1	LT Stb 30 ng/mL	Unknown			N/A	1.00	30.959	N/A	4.19e+005	4.54	Base To Base	☐	
30	I6-534006p\I6-1676.wiff	264-2	LT Stb 30 ng/mL	Unknown			N/A	1.00	32.234	N/A	4.36e+005	4.51	Base To Base	☐	
31	I6-534006p\I6-1677.wiff	264-3	LT Stb 30 ng/mL	Unknown			N/A	1.00	32.597	N/A	4.40e+005	4.49	Base To Base	☐	
32	I6-534006p\I6-1678.wiff	264-4	LT Stb 750 ng/mL	Unknown			N/A	1.00	771.82	N/A	8.39e+006	4.42	Base To Base	☐	
33	I6-534006p\I6-1679.wiff	264-5	LT Stb 750 ng/mL	Unknown			N/A	1.00	749.67	N/A	8.21e+006	4.48	Base To Base	☐	
34	I6-534006p\I6-1680.wiff	264-6	LT Stb 750 ng/mL	Unknown			N/A	1.00	759.13	N/A	8.28e+006	4.46	Base To Base	☐	
35	I6-534006p\I6-1681.wiff	257-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
36	I6-534006p\I6-1682.wiff	261-2	C 10	Standard		☒	10.000	1.00	10.104	1.0	1.41e+005	4.43	Base To Base	☐	
37	I6-534006p\I6-1683.wiff	261-5	C 30	Standard		☒	30.000	1.00	30.771	2.6	4.16e+005	4.44	Base To Base	☐	
38	I6-534006p\I6-1684.wiff	261-8	C 100	Standard		☒	100.00	1.00	98.832	-1.2	1.30e+006	4.40	Base To Base	☐	
39	I6-534006p\I6-1685.wiff	261-11	C 300	Standard		☒	300.00	1.00	298.85	-0.38	3.73e+006	4.43	Base To Base	☐	
40	I6-534006p\I6-1686.wiff	261-14	C 500	Standard		☒	500.00	1.00	489.64	-2.1	5.79e+006	4.39	Base To Base	☐	
41	I6-534006p\I6-1687.wiff	261-17	C 750	Standard		☒	750.00	1.00	754.36	0.58	8.24e+006	4.42	Base To Base	☐	
42	I6-534006p\I6-1688.wiff	261-20	C 1000	Standard		☒	1000.0	1.00	1028.5	2.8	1.03e+007	4.38	Base To Base	☐	
43	I6-534006p\I6-1689.wiff	257-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
44	I6-534006p\I6-1690.wiff	262-2	QC 30	Quality Control		☒	30.000	1.00	32.115	7.1	4.34e+005	4.32	Base To Base	☐	
45	I6-534006p\I6-1691.wiff	262-5	QC 250	Quality Control		☒	250.00	1.00	259.31	3.7	3.27e+006	4.36	Base To Base	☐	
46	I6-534006p\I6-1692.wiff	262-8	QC 750	Quality Control		☒	750.00	1.00	819.22	9.2	8.77e+006	4.37	Base To Base	☐	
47	I6-534006p\I6-1693.wiff	257-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
48	I6-534006p\I6-1694.wiff	265-1	FT Stb 30 ng/mL	Unknown			N/A	1.00	31.881	N/A	4.31e+005	4.31	Base To Base	☐	
49	I6-534006p\I6-1695.wiff	265-2	FT Stb 30 ng/mL	Unknown			N/A	1.00	32.061	N/A	4.33e+005	4.30	Base To Base	☐	
50	I6-534006p\I6-1696.wiff	265-3	FT Stb 30 ng/mL	Unknown			N/A	1.00	32.648	N/A	4.41e+005	4.30	Base To Base	☐	
51	I6-534006p\I6-1697.wiff	265-4	FT Stb 30 ng/mL	Unknown			N/A	1.00	32.715	N/A	4.42e+005	4.27	Base To Base	☐	
52	I6-534006p\I6-1698.wiff	265-5	FT Stb 30 ng/mL	Unknown			N/A	1.00	33.364	N/A	4.51e+005	4.29	Base To Base	☐	
53	I6-534006p\I6-1699.wiff	265-6	FT Stb 30 ng/mL	Unknown			N/A	1.00	32.896	N/A	4.44e+005	4.27	Valley	☐	
54	I6-534006p\I6-1700.wiff	265-7	FT Stb 30 ng/mL	Unknown			N/A	1.00	33.902	N/A	4.58e+005	4.27	Base To Base	☐	
55	I6-534006p\I6-1701.wiff	265-8	FT Stb 30 ng/mL	Unknown			N/A	1.00	33.007	N/A	4.46e+005	4.28	Base To Base	☐	
56	I6-534006p\I6-1702.wiff	265-9	FT Stb 30 ng/mL	Unknown			N/A	1.00	32.560	N/A	4.40e+005	4.28	Base To Base	☐	
57	I6-534006p\I6-1703.wiff	265-10	FT Stb 750 ng/mL	Unknown			N/A	1.00	784.28	N/A	8.49e+006	4.24	Base To Base	☐	
58	I6-534006p\I6-1704.wiff	265-11	FT Stb 750 ng/mL	Unknown			N/A	1.00	780.03	N/A	8.46e+006	4.24	Base To Base	☐	

Printing Date: Saturday, July 21, 2007

Operator: Shelly Hollar

	File Name	Sample ID	Sample Name	Sample Type	Analyte Peak Name	Use Record	Analyte Concentration (ng/mL)	Dilution Factor	Calculated Concentration (ng/mL)	%RE	Analyte Peak Area (counts)	Analyte Retention Time (min)	Analyte Integration Type	Record Modified	Sample Annotation
59	I6-534006p\I6-1705.wiff	265-12	FT Stb 750 ng/mL	Unknown			N/A	1.00	770.35	N/A	8.38e+006	4.23	Base To Base	☐	
60	I6-534006p\I6-1706.wiff	265-13	FT Stb 750 ng/mL	Unknown			N/A	1.00	768.36	N/A	8.36e+006	4.24	Base To Base	☐	
61	I6-534006p\I6-1707.wiff	265-14	FT Stb 750 ng/mL	Unknown			N/A	1.00	764.71	N/A	8.33e+006	4.23	Base To Base	☐	
62	I6-534006p\I6-1708.wiff	265-15	FT Stb 750 ng/mL	Unknown			N/A	1.00	795.48	N/A	8.58e+006	4.22	Base To Base	☐	
63	I6-534006p\I6-1709.wiff	265-16	FT Stb 750 ng/mL	Unknown			N/A	1.00	789.68	N/A	8.54e+006	4.22	Base To Base	☐	
64	I6-534006p\I6-1710.wiff	265-17	FT Stb 750 ng/mL	Unknown			N/A	1.00	791.67	N/A	8.55e+006	4.22	Base To Base	☐	
65	I6-534006p\I6-1711.wiff	265-18	FT Stb 750 ng/mL	Unknown			N/A	1.00	793.75	N/A	8.57e+006	4.24	Base To Base	☐	
66	I6-534006p\I6-1712.wiff	257-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
67	I6-534006p\I6-1713.wiff	262-3	QC 30	Quality Control		☒	30.000	1.00	33.998	13.	4.59e+005	4.22	Base To Base	☐	
68	I6-534006p\I6-1714.wiff	262-6	QC 250	Quality Control		☒	250.00	1.00	273.11	9.2	3.43e+006	4.19	Base To Base	☐	
69	I6-534006p\I6-1715.wiff	262-9	QC 750	Quality Control		☒	750.00	1.00	850.43	13.	9.02e+006	4.17	Base To Base	☐	
70	I6-534006p\I6-1716.wiff	257-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐	
71	I6-534006p\I6-1717.wiff	261-3	C 10	Standard		☒	10.000	1.00	10.842	8.4	1.51e+005	4.20	Base To Base	☐	
72	I6-534006p\I6-1718.wiff	261-6	C 30	Standard		☒	30.000	1.00	32.772	9.2	4.43e+005	4.17	Base To Base	☐	
73	I6-534006p\I6-1719.wiff	261-9	C 100	Standard		☒	100.00	1.00	105.86	5.9	1.39e+006	4.18	Base To Base	☐	
74	I6-534006p\I6-1720.wiff	261-12	C 300	Standard		☒	300.00	1.00	314.78	4.9	3.91e+006	4.19	Base To Base	☐	
75	I6-534006p\I6-1721.wiff	261-15	C 500	Standard		☒	500.00	1.00	508.36	1.7	5.98e+006	4.14	Base To Base	☐	
76	I6-534006p\I6-1722.wiff	261-18	C 750	Standard		☒	750.00	1.00	774.67	3.3	8.41e+006	4.16	Base To Base	☐	
77	I6-534006p\I6-1723.wiff	261-21	C 1000	Standard		☒	1000.0	1.00	1073.8	7.4	1.06e+007	4.15	Base To Base	☒	Peak splitting factor

Results Path: \\Lcmsp03\sciexdata\Projects\534006\Bio\Results\I6-534006p1.r
Results Name: I6-534006p1.rdb



Printing Date: Saturday, July 21, 2007
Printing Time: 10:08:35 AM

Operator: Shelly Hollar
nalyst Version: 1.4.2

Table A-16: I6-534006q1 Data

Note:

- Urine Long Term Stability
- Urine Freeze Thaw Stability

Study Record Page: 275b to 275c

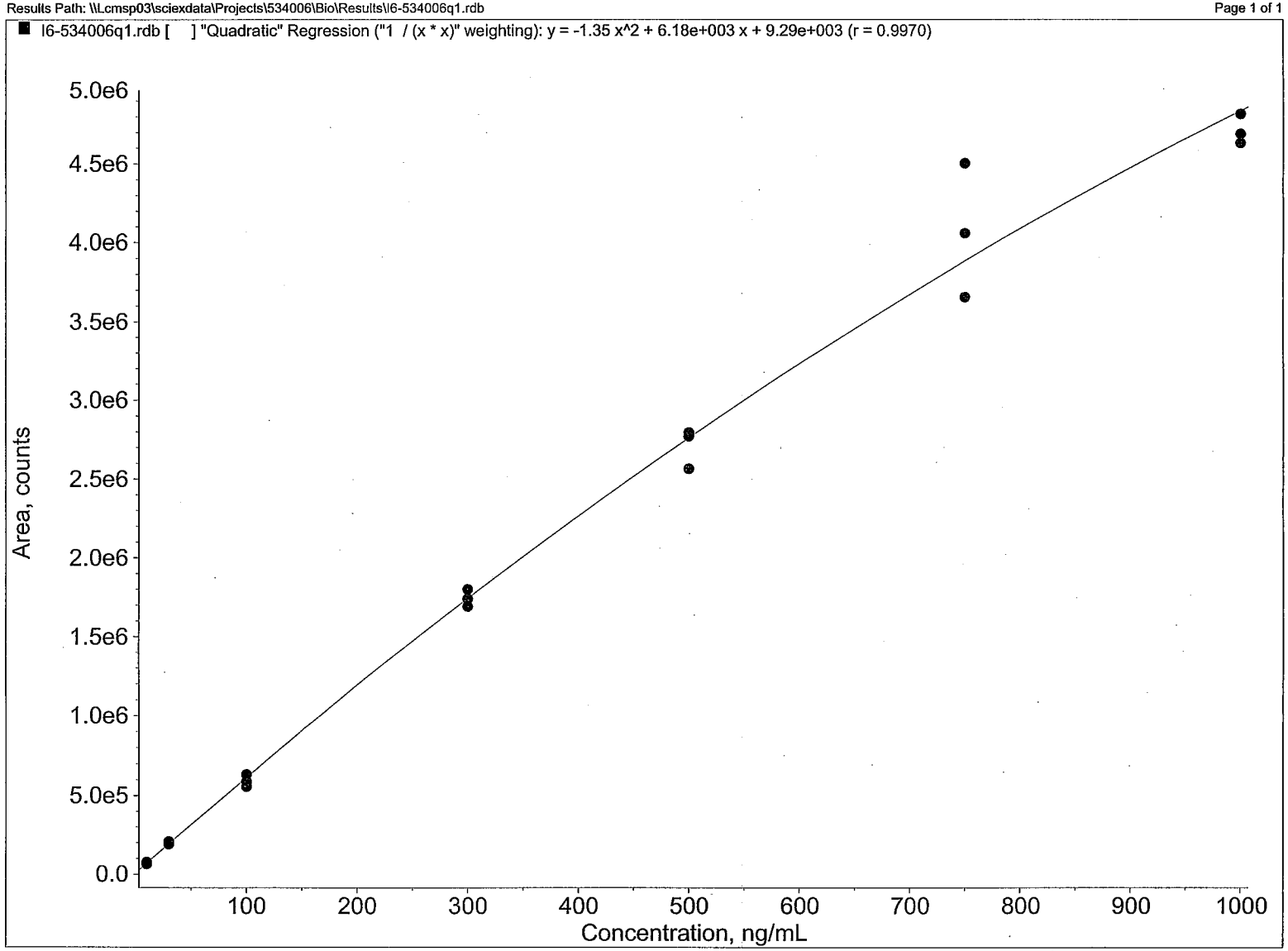
Results Path: \\Lcmsp03\sciexdata\Projects\534006\Bio\Results\I6-534006q1.rdb

	File Name	Sample ID	Sample Name	Sample Type	Analyte Peak Name	Use Record	Analyte Concentration (ng/mL)	Dilution Factor	Calculated Concentration (ng/mL)	%RE	Analyte Peak Area (counts)	Analyte Retention Time (min)	Analyte Integration Type	Record Modified	Sample Annotation	EEA
1	I6-534006q\I6-1743.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
2	I6-534006q\I6-1744.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
3	I6-534006q\I6-1745.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
4	I6-534006q\I6-1746.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
5	I6-534006q\I6-1747.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
6	I6-534006q\I6-1748.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
7	I6-534006q\I6-1749.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
8	I6-534006q\I6-1750.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
9	I6-534006q\I6-1751.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
10	I6-534006q\I6-1752.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
11	I6-534006q\I6-1753.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
12	I6-534006q\I6-1754.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
13	I6-534006q\I6-1755.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
14	I6-534006q\I6-1756.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
15	I6-534006q\I6-1757.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
16	I6-534006q\I6-1758.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
17	I6-534006q\I6-1759.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
18	I6-534006q\I6-1760.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
19	I6-534006q\I6-1761.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
20	I6-534006q\I6-1762.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
21	I6-534006q\I6-1763.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
22	I6-534006q\I6-1764.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
23	I6-534006q\I6-1765.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
24	I6-534006q\I6-1766.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
25	I6-534006q\I6-1767.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
26	I6-534006q\I6-1768.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
27	I6-534006q\I6-1769.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
28	I6-534006q\I6-1770.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
29	I6-534006q\I6-1771.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
30	I6-534006q\I6-1772.wiff	268-10	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	1.04e+007	4.73	Base To Base	☐		Test Solution
31	I6-534006q\I6-1773.wiff	268-10	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	1.03e+007	4.70	Base To Base	☐		Test Solution
32	I6-534006q\I6-1774.wiff	268-10	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	1.02e+007	4.71	Valley	☐		Test Solution
33	I6-534006q\I6-1775.wiff	268-10	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	1.03e+007	4.72	Valley	☐		Test Solution
34	I6-534006q\I6-1776.wiff	268-10	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	1.04e+007	4.72	Base To Base	☐		Test Solution
35	I6-534006q\I6-1777.wiff	268-10	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	1.04e+007	4.70	Valley	☐		Test Solution
36	I6-534006q\I6-1778.wiff	268-10	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	1.03e+007	4.70	Base To Base	☐		Test Solution
37	I6-534006q\I6-1779.wiff	268-10	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	1.04e+007	4.74	Base To Base	☐		Test Solution
38	I6-534006q\I6-1780.wiff	268-10	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	1.04e+007	4.72	Base To Base	☐		Test Solution
39	I6-534006q\I6-1781.wiff	268-10	Test Solution	Unknown			N/A	1.00	No Intercept	#BAD!	1.04e+007	4.70	Base To Base	☐		Test Solution
40	I6-534006q\I6-1782.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
41	I6-534006q\I6-1783.wiff	272-1	Solvent Blank	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Solvent Blank
42	I6-534006q\I6-1784.wiff	272-2	Blank Urine	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Blank Urine
43	I6-534006q\I6-1785.wiff	272-3	Blank Urine	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Blank Urine
44	I6-534006q\I6-1786.wiff	272-4	Blank Urine	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Blank Urine
45	I6-534006q\I6-1787.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
46	I6-534006q\I6-1788.wiff	270-1	C 10	Standard		☒	10.000	1.00	9.0316	-9.7	6.50e+004	4.76	Base To Base	☐		C 10
47	I6-534006q\I6-1789.wiff	270-4	C 30	Standard		☒	30.000	1.00	29.429	-1.9	1.90e+005	4.75	Base To Base	☐		C 30
48	I6-534006q\I6-1790.wiff	270-7	C 100	Standard		☒	100.00	1.00	90.510	-9.5	5.57e+005	4.75	Base To Base	☐		C 100
49	I6-534006q\I6-1791.wiff	270-10	C 300	Standard		☒	300.00	1.00	290.66	-3.1	1.69e+006	4.77	Base To Base	☐		C 300
50	I6-534006q\I6-1792.wiff	270-13	C 500	Standard		☒	500.00	1.00	501.88	0.38	2.77e+006	4.77	Base To Base	☐		C 500
51	I6-534006q\I6-1793.wiff	270-16	C 750	Standard		☒	750.00	1.00	792.45	5.7	4.06e+006	4.78	Base To Base	☐		C 750
52	I6-534006q\I6-1794.wiff	270-19	C 1000	Standard		☒	1000.0	1.00	942.22	-5.8	4.63e+006	4.76	Base To Base	☐		C 1000
53	I6-534006q\I6-1795.wiff	267-1	Mobile Phase	Unknown		*	N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
54	I6-534006q\I6-1796.wiff	271-1	QC 30	Quality Control		☒	30.000	1.00	32.138	7.1	2.06e+005	4.76	Base To Base	☐		QC 30
55	I6-534006q\I6-1797.wiff	271-4	QC 250	Quality Control		☒	250.00	1.00	216.43	-13.	1.28e+006	4.77	Base To Base	☐		QC 250
56	I6-534006q\I6-1798.wiff	271-7	QC 750	Quality Control		☒	750.00	1.00	811.98	8.3	4.14e+006	4.76	Base To Base	☐		QC 750
57	I6-534006q\I6-1799.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
58	I6-534006q\I6-1800.wiff	273-1	LT Stb 30 ng/mL	Unknown			N/A	1.00	31.352	N/A	2.02e+005	4.75	Base To Base	☐		LT Stb 30 ng/mL
59	I6-534006q\I6-1801.wiff	273-2	LT Stb 30 ng/mL	Unknown			N/A	1.00	25.687	N/A	1.67e+005	4.74	Base To Base	☐		LT Stb 30 ng/mL
60	I6-534006q\I6-1802.wiff	273-3	LT Stb 30 ng/mL	Unknown			N/A	1.00	29.802	N/A	1.92e+005	4.72	Base To Base	☐		LT Stb 30 ng/mL
61	I6-534006q\I6-1803.wiff	273-4	LT Stb 750 ng/mL	Unknown			N/A	1.00	782.42	N/A	4.02e+006	4.73	Base To Base	☐		LT Stb 750 ng/m
62	I6-534006q\I6-1804.wiff	273-5	LT Stb 750 ng/mL	Unknown			N/A	1.00	844.60	N/A	4.26e+006	4.73	Base To Base	☐		LT Stb 750 ng/m

Printing Date: Monday, July 30, 2007

Operator: Shelly Hollar

	File Name	Sample ID	Sample Name	Sample Type	Analyte Peak Name	Use Record	Analyte Concentration (ng/mL)	Dilution Factor	Calculated Concentration (ng/mL)	%RE	Analyte Peak Area (counts)	Analyte Retention Time (min)	Analyte Integration Type	Record Modified	Sample Annotation	EEA
63	l6-534006q\l6-1805.wiff	273-6	LT Stb 750 ng/mL	Unknown			N/A	1.00	881.42	N/A	4.41e+006	4.73	Base To Base	☐		LT Stb 750 ng/m
64	l6-534006q\l6-1806.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
65	l6-534006q\l6-1807.wiff	270-2	C 10	Standard		☒	10.000	1.00	11.033	10.	7.73e+004	4.72	Base To Base	☐		C 10
66	l6-534006q\l6-1808.wiff	270-5	C 30	Standard		☒	30.000	1.00	32.296	7.7	2.07e+005	4.76	Base To Base	☐		C 30
67	l6-534006q\l6-1809.wiff	270-8	C 100	Standard		☒	100.00	1.00	95.955	-4.0	5.89e+005	4.74	Base To Base	☐		C 100
68	l6-534006q\l6-1810.wiff	270-11	C 300	Standard		☒	300.00	1.00	299.35	-0.22	1.74e+006	4.73	Base To Base	☐		C 300
69	l6-534006q\l6-1811.wiff	270-14	C 500	Standard		☒	500.00	1.00	507.04	1.4	2.79e+006	4.76	Base To Base	☐		C 500
70	l6-534006q\l6-1812.wiff	270-17	C 750	Standard		☒	750.00	1.00	907.23	21.	4.50e+006	4.76	Base To Base	☐		C 750
71	l6-534006q\l6-1813.wiff	270-20	C 1000	Standard		☒	1000.0	1.00	958.52	-4.1	4.69e+006	4.75	Base To Base	☐		C 1000
72	l6-534006q\l6-1814.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
73	l6-534006q\l6-1815.wiff	271-2	QC 30	Quality Control		☒	30.000	1.00	31.410	4.7	2.02e+005	4.75	Base To Base	☐		QC 30
74	l6-534006q\l6-1816.wiff	271-5	QC 250	Quality Control		☒	250.00	1.00	232.45	-7.0	1.37e+006	4.74	Base To Base	☐		QC 250
75	l6-534006q\l6-1817.wiff	271-8	QC 750	Quality Control		☒	750.00	1.00	711.35	-5.2	3.72e+006	4.73	Base To Base	☐		QC 750
76	l6-534006q\l6-1818.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
77	l6-534006q\l6-1819.wiff	274-1	FT Stb 30 ng/mL	Unknown			N/A	1.00	32.932	N/A	2.11e+005	4.74	Base To Base	☐		FT Stb 30 ng/mL
78	l6-534006q\l6-1820.wiff	274-2	FT Stb 30 ng/mL	Unknown			N/A	1.00	29.877	N/A	1.93e+005	4.77	Base To Base	☐		FT Stb 30 ng/mL
79	l6-534006q\l6-1821.wiff	274-3	FT Stb 30 ng/mL	Unknown			N/A	1.00	29.460	N/A	1.90e+005	4.73	Base To Base	☐		FT Stb 30 ng/mL
80	l6-534006q\l6-1822.wiff	274-4	FT Stb 750 ng/mL	Unknown			N/A	1.00	830.31	N/A	4.21e+006	4.72	Base To Base	☐		FT Stb 750 ng/m
81	l6-534006q\l6-1823.wiff	274-5	FT Stb 750 ng/mL	Unknown			N/A	1.00	769.97	N/A	3.97e+006	4.73	Valley	☐		FT Stb 750 ng/m
82	l6-534006q\l6-1824.wiff	274-6	FT Stb 750 ng/mL	Unknown			N/A	1.00	876.16	N/A	4.39e+006	4.72	Base To Base	☐		FT Stb 750 ng/m
83	l6-534006q\l6-1825.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
84	l6-534006q\l6-1826.wiff	271-3	QC 30	Quality Control		☒	30.000	1.00	28.890	-3.7	1.87e+005	4.75	Base To Base	☐		QC 30
85	l6-534006q\l6-1827.wiff	271-6	QC 250	Quality Control		☒	250.00	1.00	233.37	-6.7	1.38e+006	4.75	Base To Base	☐		QC 250
86	l6-534006q\l6-1828.wiff	271-9	QC 750	Quality Control		☒	750.00	1.00	749.42	-0.077	3.88e+006	4.75	Valley	☐		QC 750
87	l6-534006q\l6-1829.wiff	267-1	Mobile Phase	Unknown			N/A	1.00	No Peak	N/A	0.00e+000	0.00	No Peak	☐		Mobile Phase
88	l6-534006q\l6-1830.wiff	270-3	C 10	Standard		☒	10.000	1.00	9.6527	-3.5	6.88e+004	4.74	Base To Base	☐		C 10
89	l6-534006q\l6-1831.wiff	270-6	C 30	Standard		☒	30.000	1.00	31.740	5.8	2.04e+005	4.75	Base To Base	☐		C 30
90	l6-534006q\l6-1832.wiff	270-9	C 100	Standard		☒	100.00	1.00	103.21	3.2	6.32e+005	4.74	Base To Base	☐		C 100
91	l6-534006q\l6-1833.wiff	270-12	C 300	Standard		☒	300.00	1.00	310.58	3.5	1.80e+006	4.74	Base To Base	☐		C 300
92	l6-534006q\l6-1834.wiff	270-15	C 500	Standard		☒	500.00	1.00	459.59	-8.1	2.56e+006	4.73	Base To Base	☐		C 500
93	l6-534006q\l6-1835.wiff	270-18	C 750	Standard		☒	750.00	1.00	696.11	-7.2	3.66e+006	4.75	Base To Base	☐		C 750
94	l6-534006q\l6-1836.wiff	270-21	C 1000	Standard		☒	1000.0	1.00	994.27	-0.57	4.82e+006	4.75	Base To Base	☐		C 1000


I6-534006q1.rdb [ ] "Quadratic" Regression ("1 / (x * x)" weighting): y = -1.35 x^2 + 6.18e+003 x + 9.29e+003 (r = 0.9970)
Area, counts
5.0e6
4.5e6
4.0e6
3.5e6
3.0e6
2.5e6
2.0e6
1.5e6
1.0e6
5.0e5
0.0
100
200
300
400
500
600
700
800
900
1000
Concentration, ng/mL

APPENDIX F

Toxicokinetic Report [ ]

534006

STUDY TITLE

PHARMACOKINETIC (IN BLOOD)
AND EXCRETION STUDY OF [ ] IN RATS

REPORT TITLE

PHARMACOKINETICS OF [ ] IN SERUM AND URINE FOLLOWING A SINGLE INTRAVENOUS DOSE TO RATS

REPORT DATE

26 September 2007

FINAL REPORT

Sponsor	Testing Facility
[ ]	[ ]

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1.0 SUMMARY

One group of nine male and nine female Crl:CD®(SD) rats received a single intravenous (bolus) injection of difluoro [

] at a dosage of 10 mg/kg at a dosage volume of 5 mL/kg. Blood samples were collected from three animals/sex/group at 0 (prior to dosing), 2, 10, 20, and 30 minutes and 1, 3, 5, 7, 24, and 48 hours after dosing.

For the urine excretion phase, one group of three male and three female Crl:CD®(SD) rats received a single intravenous (bolus) injection of [ ] at a dosage level of 10 mg/kg at a dosage volume of 5 mL/kg. Urine was collected from each animal over the following intervals: 0-6, 6-12, and 12-24 hours post-dosing. After each urine collection, cages were rinsed and the rinses were collected separately for analysis.

The concentration of [ ] in the serum, urine, and cage rinse samples was measured using a validated LC-MS/MS method. The serum concentration immediately following the intravenous dose was estimated based on a regression analysis of the measured values. The mean concentrations in serum and mean amounts excreted in urine plus cage rinse were used for pharmacokinetic analysis.

The pharmacokinetic parameters for [ ] are summarized in the following table:

PHARMACOKINETIC RESULTS FOR [ ]									
[ ]	SERUM						URINE†		
10 mg/kg Intravenous Dose	C_0* (ng/mL)	$AUC_{0-\infty}$ (ng×h/mL)	K_{el} (h^{-1})	Half-life** (h)	Cl (L/h×kg)	V_d (L/kg)	K_{el} (h^{-1})	Half-life** * (h)	% of Dose Elimi-nated
Males	69775	373393	0.127	5.4	0.0268	0.210	0.215	3.2	67.3
Females	102835	53137	0.074	9.4	0.188	2.55	0.392	1.8	64.0

* Values were estimated.
**For the terminal elimination phase.
***For urinary elimination.
†Urine plus cage rinse

After a single intravenous dose of [ ] at 10 mg/kg, systemic exposure ($AUC_{0-\infty}$) to [ ] for male rats was almost 7-fold higher than for female rats. [ ] appeared to remain mostly in the circulation in male rats (apparent volume of distribution about 0.2 L/kg), but to have extensive tissue distribution in female rats (apparent volume of distribution of more than 2.5 L/kg). The terminal elimination phase for [ ] in serum had a half-life of 9.4 and 5.4 hours for female and male rats, respectively. The half-life for [ ] in urine was 1.8 and 3.2 hours, for female and male rats respectively. Nevertheless, the percent of [ ] dose eliminated over 24 hours post-dosing in the urine of male rats and female rats was similar (approximately 65%). This can be explained by the lower amounts of [ ] available for urinary clearance in the circulation of female rats compared to male rats as suggested by the differences in apparent volume distribution.

2.0 INTRODUCTION

One group of nine male and nine female Crl:CD®(SD) rats received a single intravenous (bolus) injection of difluoro [

] at a dosage of 10 mg/kg at a dosage volume of 5 mL/kg. Blood samples were collected from three animals/sex/group at 0 (prior to dosing), 2, 10, 20, and 30 minutes and 1, 3, 5, 7, 24, and 48 hours after dosing. Blood samples (approximately 0.5 mL) were collected via a retro-orbital sinus into tubes containing no anticoagulant while the animal was under isoflurane anesthesia. Serum was separated using a refrigerated centrifuge. Samples were stored at approximately -20°C until transferred to the Analytical Chemistry Department [ ], then stored at -70°C until analysis.

For the urine excretion phase, one group of three male and three female Crl:CD®(SD) rats received a single intravenous (bolus) injection of [ ] at a dosage level of 10 mg/kg at a dosage volume of 5 mL/kg. Urine was collected from each animal over the following intervals: 0-6, 6-12, and 12-24 hours post-dosing. After each urine collection, cages were rinsed and the rinses were collected separately for analysis. Urine samples were maintained on wet ice during collection. Samples were stored at approximately -70°C until transferred to the Analytical Chemistry Department of [ ], then stored at -20°C until analysis..

The concentration of [ ] in serum, urine and cage rinse samples were measured by the Analytical Chemistry Department at [ ] using a validated

LC-MS/MS method. The serum concentration immediately following the intravenous dose was estimated based on a regression analysis of the measured values. The mean concentrations in serum and mean amounts excreted in urine (plus cage rinse) were used for pharmacokinetic analysis.

3.0 EXPERIMENTAL

3.1 Data Processing

All calculations were performed using Microsoft® Excel 2002 on a Microsoft® Windows XP Professional platform. Graphical presentations were created using SigmaPlot 2004 for Windows Version 9.0.

3.2 Bioanalysis

Concentration of [ ] in serum, urine, and cage rinse samples were measured using a validated LC-MS/MS method by the Analytical Chemistry Department at [

]. A detailed description of the analytical method and the results for each sample may be found in Appendix E. The lower limit of quantitation (LLOQ) was 10 ng/mL for serum, urine and cage rinse.

3.3 Toxicokinetic Evaluation & Statistical Analysis

In the calculation of the toxicokinetic parameters, samples were assigned a value of zero if the concentration was below the LLOQ. All toxicokinetic parameters were calculated

from the mean serum or urine (plus cage rinse) concentration data as indicated in the following table:

C_0	The estimated concentration of the compound in serum immediately following intravenous administration. The values were set equal to the y-intercept of the linear regression based on the log concentration of the mean values from 2 to 20 minutes post-dosing.
AUC_{0-t}	The area under the serum concentration vs. time curve from the time of dosing to C_{last} (the last mean serum concentration > 0). The values were calculated by linear trapezoidal summation using the equation: $$AUC_{0-t} = \Sigma\ (0.5 \cdot (y_1 + y_2) \cdot \Delta t)$$ where y_1 and y_2 are successive serum concentrations and Δt is the sampling interval, in hours, between y_1 and y_2.
$AUC_{0-\infty}$	The estimate of the area under the serum concentration vs. time curve from time of dosing to infinity. The values were calculated using the formula: $$AUC_{0-\infty} = AUC_{0-t} + (C_{last}/K_{el})$$ where AUC_{0-t} and C_{last} were defined previously, and K_{el} is defined subsequently.
K_{el}	The terminal elimination rate constant for the compound in serum or urine. The values were calculated using the equation: $$K_{el} = -\ln[10] \times b$$ where b is the slope of the least-squares linear regression line of the log serum concentrations from 7 to 48 hours post-dosing or the log ARE from 0 to 12 hours post-dosing and ARE is defined subsequently.
Half-life	The half-life for the compound in serum or the half-life of urinary elimination. The values were calculated using the formula: $$\text{Half-life} = -\ln[0.5]/K_{el}$$ where K_{el} is defined previously.

Cl	The apparent systemic clearance for the compound in serum. The values were calculated using the formula: $Cl = Dosage/AUC_{0-\infty}$ where $AUC_{0-\infty}$ is defined previously.
V_d	The apparent volume of distribution for the compound in serum. The values were calculated using the formula: $V_d = Cl/K_{el}$ where Cl and K_{el} are defined previously.
ARE	The amount remaining to be eliminated in urine. The values were calculated using the formula: ARE = Total amount eliminated – Amount eliminated in previous interval(s)
Urinary Elimination as % Dose	The total amount eliminated in urine expressed as a percentage of the analyte dose. The value was calculated using the equation: Total as % Dose = 100 × ARE at 0 h/(Mean BW × Dosage) where ARE is defined previously and BW is the mean body weight used to calculate the administered dose. Mean body weights were obtained from Table 6 of the main report.

4.0 RESULTS AND DISCUSSION

4.1 Serum Concentration Data

The concentration of [ ] in individual serum samples can be found in the tables of the bioanalytical report (Appendix E).

Mean serum concentrations of [ ] following a single intravenous dose at 10 mg [ ]/kg to male and female rats are presented in Table 1 and illustrated in Figure 1. The dose for Animal No. 46669 (male) appeared to be delivered extravascularly; mean and

SD serum [ ] concentrations for the males are presented with and without the data for this animal.

Table 1. Mean ± SD Concentrations of [ ] in Serum of Male Rats following Intravenous Administration of 10 mg [ ]/kg

Hours Post-Dosing	Males		Males*		Females	
	Mean (ng/mL)	SD	Mean (ng/mL)	SD	Mean (ng/mL)	SD
Pre-dose	0.00	0.00	0.00	0.00	0.00	0.00
C_0**	69775	N/A	93101	N/A	102835	N/A
0.0333	67655	44748	93115	10756	94742	5213
0.167	69129	8686	69129	10756	50222	5972
0.333	62353	5666	62353	5666	30007	2019
0.5	43079	20222	54631	4142	23715	3816
1	63725	17015	63725	17015	14424	3930
3	24953	11314	24953	11314	882	223
5	15750	6318	13287	6590	361	248
7	17372	9052	17372	9052	220	170
24	192	177	192	177	11.8	1.71
48	73.1	90.9	20.6	3.33	8.98	7.78

*Data for Animal No. 46669 at 0.033, 0.5, 5 and 48 hours post-dosing were excluded from the calculation of mean and SD values.
**Estimated value. N/A = not applicable

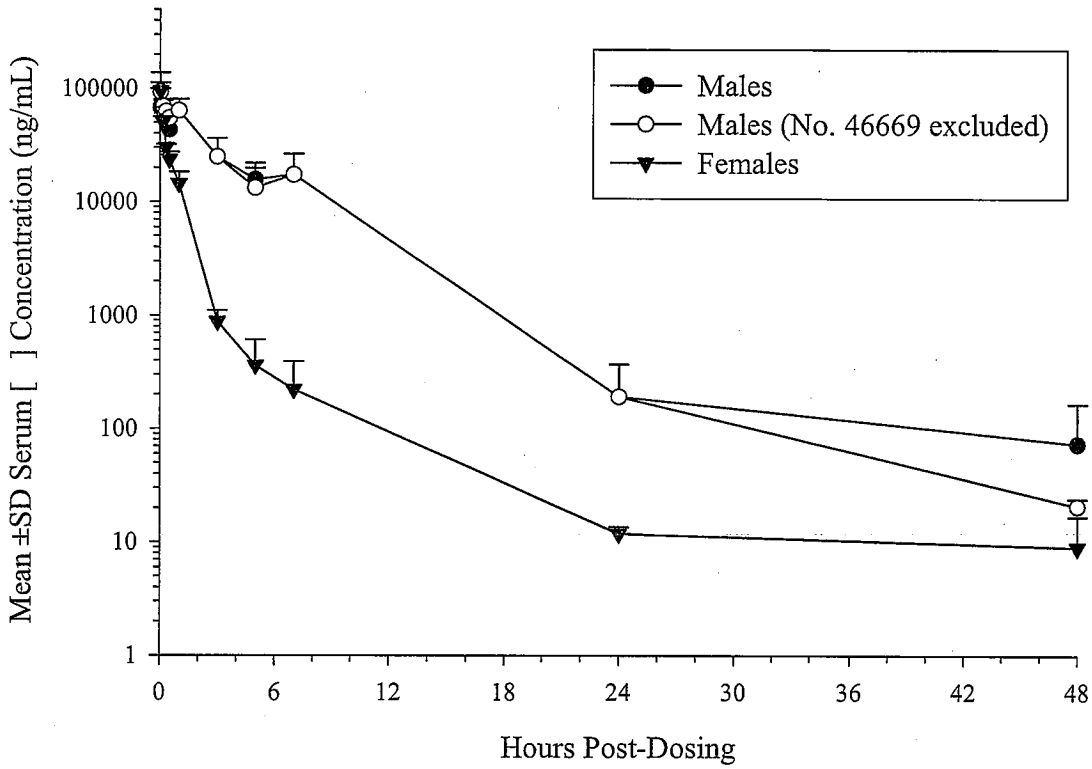

Figure 1. Mean + SD Concentrations of [ ] in Serum following Intravenous Administration of 10 mg [ ]/kg to Male and Female Rats

Concentration of [ ] in serum of male and female rats after single intravenous administration of [ ] at 10 mg/kg was measurable up to 48 hours post-dosing. Elimination of [ ] in serum appeared to multi-phasic in both male and female rats; however, the temporal trends in serum concentration profiles differed between the genders. In male rats, serum [ ] concentration remained relatively constant through 1 hour post-dosing, decreased gradually from 1 to 7 hours post-dosing and then decreased

further from 7 through 48 hours post-dosing. In female rats, serum [ ] concentration decreased rapidly through 3 hours post-dosing, decreased more gradually from 3 to 24 hours post-dosing and then decreased only slightly from 24 through 48 hours post-dosing.

4.2 [ ] Elimination in Urine

The concentration of [ ] in individual urine samples can be found in the tables of the bioanalytical report (Appendix E).

Mean amounts of [ ] eliminated in urine following a single intravenous dose at 10 mg [ ]/kg to male and female rats are presented in Table 2. The cumulative percent of [ ] dose eliminated in urine is illustrated in Figure 2 and the amounts of [ ] remaining to be eliminated in urine are illustrated in Figure 3.

Table 2. Mean ± SD Amounts of [ ] in Urine following Intravenous Administration of 10 mg [ ]kg to Male and Female Rats

Hours Post-Dosing	Males		Females	
	Mean (µg)	SD	Mean (µg)	SD
0-6	878	227	773	132
6-12	571	89.8	300	216
12-24	119	22.2	9.80	3.04

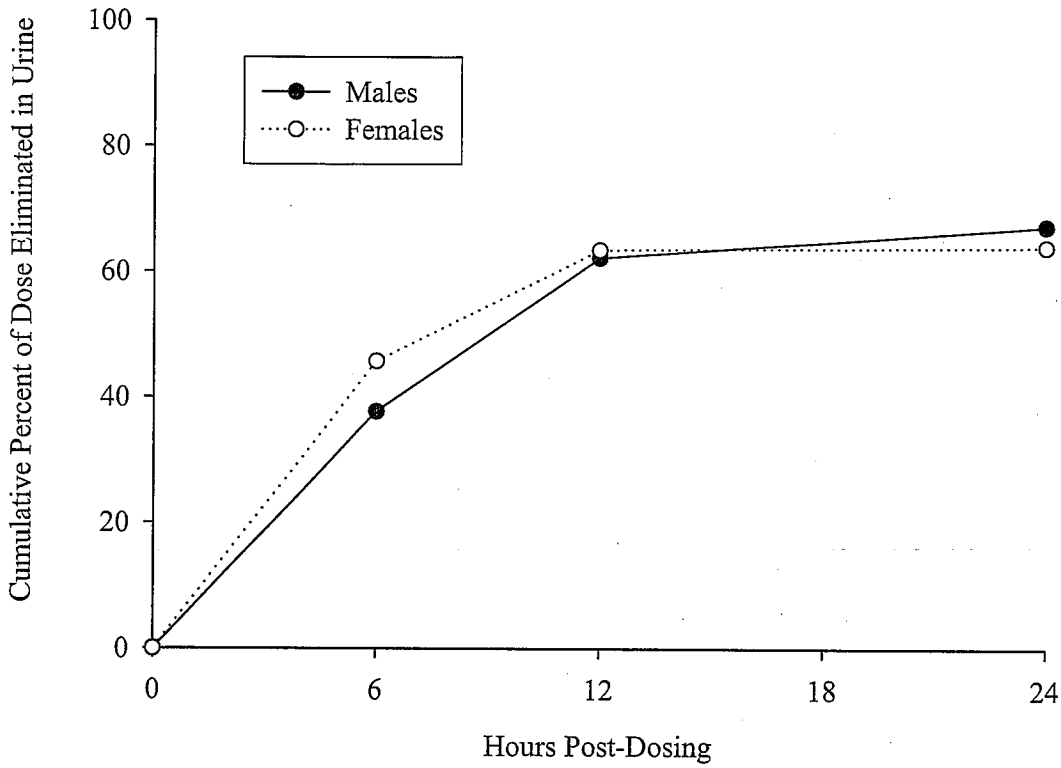

Figure 2. Cumulative Percent of Dose Eliminated in Urine following Intravenous Administration of 10 mg [ ]/kg to Male and Female Rats

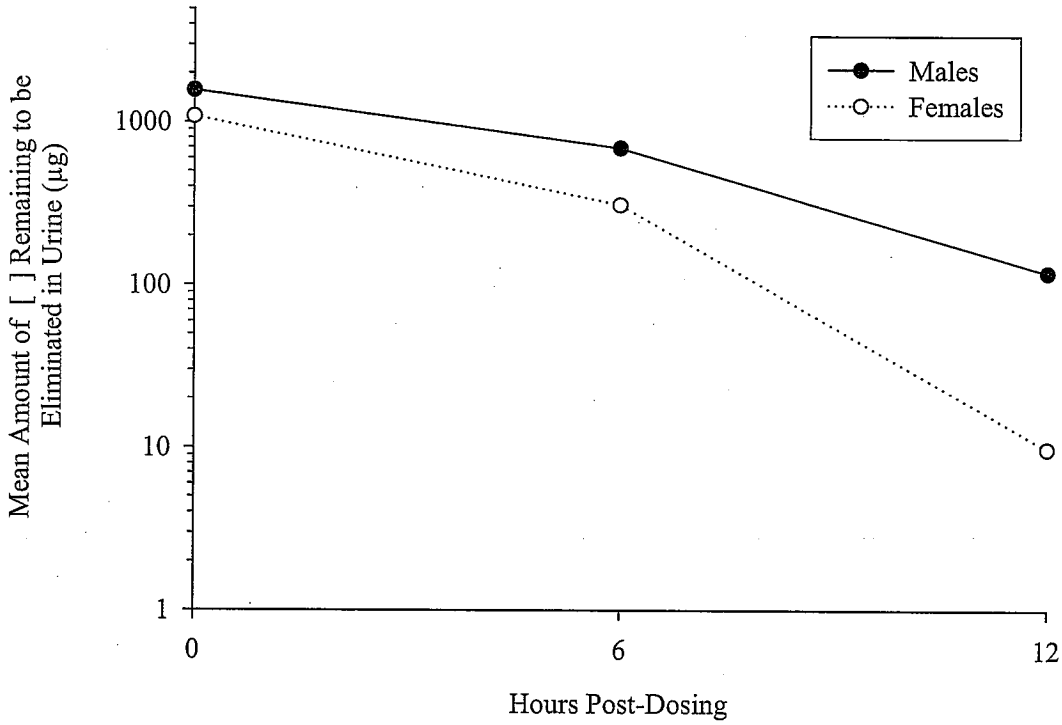

Figure 3. Mean Amount of [ ] Dose Remaining to Be Eliminated in Urine of Male and Female Rats following Intravenous Administration of 10 mg [ ]/kg

The amount of [ ] recovered in the urine accounted for approximately 67% of the administered dose for male rats and about 64% for female rats. Most of the [ ] dose was eliminated in urine over 12 hours post-dosing in both genders. The elimination of [ ] in the urine of male rats appeared to be mono-exponential; in female rats, elimination of [ ] in urine appeared not to be log-linear.

4.3 [ ] Pharmacokinetics

The pharmacokinetic parameters for [ ] in serum of male and female rats are presented in Table 3.

Table 3. Pharmacokinetic Parameters for [ ] in Serum following Intravenous Administration of 10 mg [ ]/kg to Male and Female Rats

	AUC_{0-t} (ng×h/mL)	$AUC_{0-\infty}$ (ng×h/mL)	K_{el} (h^{-1})*	Half-life (h)*	Cl (L/h×kg)	V_d (L/kg)
Males	372819	373393	0.127	5.4	0.0268	0.210
(Males)**	(373629)	(373758)	(0.160)	(4.3)	(0.0268)	(0.168)
Females	53015	53137	0.0737	9.4	0.188	2.55

* For the terminal elimination phase.
** Data for Animal No. 46669 were excluded from the calculation of the pharmacokinetic parameters.

The pharmacokinetic parameters for [ ] differed between the genders. Systemic exposure ($AUC_{0-\infty}$) for male rats was almost 7-fold higher than for female rats. This may be attributable to gender differences in the tissue distribution of [ ] in rats. In male rats, [ ] appeared to remain mostly in circulation (apparent volume of distribution about 0.2 L/kg). In female rats, [ ] appeared to have extensive tissue distribution (apparent volume of distribution of more than 2.5 L/kg). The terminal elimination phase for [ ] in serum had a half-life of 9.4 and 5.4 hours, for female and male rats respectively. Exclusion of the serum concentration data for Animal No. 46669 had negligible effect on most of the pharmacokinetic parameters for male rats.

Pharmacokinetic parameters for [ ] in urine following a single intravenous dose at 10 mg [ ]/kg to male and female rats are presented in Table 4.

Table 4. Pharmacokinetic Parameters for [ ] in Urine following Intravenous Administration of 10 mg [ ]/kg to Male and Female Rats

	Total Eliminated as a % of Dose	Elimination Rate Constant (1/h)*	Half-life (h)*
Males	67.3	0.215	3.2
Females	64.0	0.392	1.8

*Based on 0-12 h.

The half-life for [ ] in urine was 1.8 and 3.2 hours, for female and male rats respectively. Nevertheless, the percent of [ ] dose eliminated over 24 hours post-dosing in the urine of male rats and female rats was similar (approximately 65%). This can be explained by the lower amounts of [ ] available for urinary clearance in the circulation of female rats compared to male rats as suggested by the differences in apparent volume distribution.

5.0 CONCLUSIONS

After a single intravenous dose of [ ] at 10 mg/kg, systemic exposure ($AUC_{0-\infty}$) to [ ] for male rats was almost 7-fold higher than for female rats. [ ] appeared to remain mostly in the circulation in male rats (apparent volume of distribution about 0.2 L/kg), but to have extensive tissue distribution in female rats (apparent volume of distribution of more than 2.5 L/kg). The terminal elimination phase for [ ] in serum had a half-life of 9.4 and 5.4 hours for female and male rats, respectively. The half-life for [ ] in urine was 1.8 and 3.2 hours, for female and male rats respectively. Nevertheless, the percent of [ ] dose eliminated over 24 hours post-dosing in the urine of male rats and female rats was similar (approximately 65%). This can be explained by the lower amounts of [ ] available for urinary clearance in the circulation of female rats compared to male rats as suggested by the differences in apparent volume distribution.

APPENDIX G

Study Protocol

PROTOCOL AMENDMENT I

A. Title of Study:

Pharmacokinetic (in Blood) and Excretion Study of

B. Protocol Modification:

1) **3** **STUDY SCHEDULE:**

Proposed Experimental Termination (Completion) Date: April 5, 2007 (last bioanalytical analysis)

2) **4.1** **Identification:**

8.5 **Toxicokinetics for Elimination:**

3) In accordance with the study director notification dated December 11, 2006, serum and urine samples for toxicokinetic evaluation will be stored at approximately -20°C or lower.

4) In accordance with the study director notification dated May 3, 2007, the [redacted] urine for each animal at each time point will be calculated as the sum of total [redacted] urine and from the urine rinse sample.

5) Also in accordance with the study director notification dated May 3, 2007, the last sentence of this section of the protocol is amended to read as follows:

Subsequently, pertinent toxicokinetic parameters, such as C_{max}, AUC, and elimination half-life, will be determined as data permit, following a single dose of the test material.

6) **8.6** **Anatomic Pathology:**

In accordance with the study director notification dated December 13, 2006, this section is added to the protocol. A gross macroscopic examination will be performed on any animals found dead or euthanized *in extremis*. Animals euthanized *in extremis* will be euthanized by CO_2 inhalation. No tissues will be collected.

C. Reason for Protocol Modification:

1) Addition of Experimental Termination (Completion) date.

2) Correction of typographical error.

3) Clarification of storage conditions for serum and urine samples.

4) Addition of method for calculation of total

5) Clarification of wording for a single test material.

6) Addition of gross necropsy for animals found dead or euthanized *in extremis*.

28 June, 2007
Date

22 June 2007
Date

22 June 2007
Date

PROTOCOL

PHARMACOKINETIC (IN BLOOD) AND EXCRETION STUDY OF

Submitted To:

1 OBJECTIVE:

The objective of this study is to evaluate the pharmacokinetic (in blood) and excretion profiles of the test article in rats.

This protocol has been designed and the study will be conducted in compliance with the U.S. Environmental Protection Agency, 40 CFR Part 792, and the Organisation for Economic Cooperation and Development [C(97)186/Final] Good Laboratory Practice (GLP) Regulations. This study will be performed according to the protocol dard Operating Procedures.

2 PERSONNEL INVOLVED IN THE STUDY:

2.1 Sponsor Representative:

2.2

2.3

2.4

4 TEST ARTICLE DATA:

4.1 Identification:

4.2 Lot Number:

To be provided by the Sponsor.

4.3 Purity:

99.0%. The purity will be considered to be 100% for the purpose of dosage calculations.

4.4 Stability:

The test article is considered to be stable under the storage conditions provided by the Sponsor.

4.5 Physical Description:

To be documen

4.6 Storage Conditions:

To be provided by the Sponsor.

4.7 Reserve Samples:

Retention samples will be collected and stored in accordance with Standard Operating Procedures.

4.8 Personnel Safety Information:

To be provided by the Sponsor. It is the responsibility of the Sponsor to notify the testing facility of any special handling requirements for the test article. A material safety data sheet (MSDS) should accompany the test article upon arrival at the laboratory.

4.9 Vehicle:

Sterile water for injection.

5 TEST SYSTEM:

5.1 Species:

Rat

5.2 Strain:

Sprague-Dawley Crl:CD®(SD)

5.3 Source:

Charles River Laboratories, Inc.
(Facility to be documented in the study records)

5.4 Number on Study:

Fifteen (15) animals of each sex will be ordered. Twelve males and 12 females will be placed on study. Animals not utilized on study will be deemed as part of the stock colony or euthanized by CO_2 inhalation and discarded.

5.5 Approximate Age and Weight:

Animals will be approximately 5 to 7 weeks of age when received and 7 to 9 weeks of age at initiation of dosing. Body weight will be approximately 200 to 350 grams at initiation of dosing.

5.6 Identification System:

The animals will be uniquely identified by a metal eartag displaying the animal number. Individual cage cards will be affixed to each cage and will display the animal number, group number, study number, dosage level and sex of the animal.

5.7 Justification for Selection and Number on Study:

This species and strain of animal is recognized to be appropriate for subchronic toxicity studies. The Sprague-Dawley rat will be used because it is a widely used strain for which significant historical control data are available. This number of animals is considered to be the minimum required for meaningful interpretation of the data and fulfillment of agency requirements.

6 SPECIFIC MAINTENANCE SCHEDULE:

6.1 Animal Housing:

Animals will be housed in a study-dedicated, environmentally controlled room three per cage by sex in clean, suspended, wire-mesh cages for approximately two to four days following receipt. If the number of animals received does not allow for all animals to be housed three per cage by sex, then some animals will be pair-housed by sex. Thereafter, all animals will be housed individually. The cages will be elevated above cage-board or other suitable material which will be changed at least three times each week. The facilities at [redacted] fully accredited by the Association for [redacted] of Laboratory Animal Care International (AAALAC International).

6.2 Environmental Conditions:

Controls will be set to maintain an average daily temperature of 71 ± 5°F (22 ± 3°C) and an average daily relative humidity of 50 ± 20%. Temperature and relative humidity will be monitored continuously. Data for these two parameters will be scheduled for automatic collection on an hourly basis. Fluorescent lighting controlled by light timers will provide illumination for a 12 hour light/dark photoperiod. Temporary adjustments to the light/dark cycles may be made to accommodate protocol specified activities. The ventilation rate will be set at a minimum of 10 room air changes per hour, 100% fresh air.

6.3 Drinking Water:

Reverse osmosis-purified water will be available *ad libitum*. Filters servicing the automatic watering system are changed regularly according to Standard Operating Procedures. The municipal water supplying the labo[redacted] is analyzed according to [redacted] routine basis to assure that contaminants are not present in concentrations that would be expected to affect the outcome of the study.

6.4 Basal Diet:

PMI Nutrition International, LLC Certified Rodent LabDiet® 5002 (meal) will be offered *ad libitum* during the study. Periodic analyses of the certified feed are performed by the manufacturer to ensure that heavy metals and pesticides are not present at concentrations that would be expected to affect the outcome of the study. Results of the analyses are provided to [redacted] change

7 EXPERIMENTAL DESIGN:

7.1 Animal Receipt and Quarantine:

Each animal will be inspected by a qualified technician upon receipt. Animals judged to be in good health will be placed immediately in acclimation for at least seven days. All animals will be weighed and assigned a permanent animal number. During the acclimation period, each animal will be observed twice daily for changes in general appearance and behavior. There will be a pretreatment week (as part of the acclimation period) during which body weights and food consumption will be recorded and general health will be monitored, but the rats will not be dosed. All animals will receive a detailed physical examination at the initiation of pretest and at the time of animal selection for randomization.

7.2 Randomization:

At the conclusion of the acclimation period, animals judged to be suitable for testing will be assigned to groups at random, based on body weight stratification into a block design, using a computer program. A printout containing the animal numbers and individual group assignments will be generated. Animals will then be arranged into the groups according to the printout. Body weights at randomization will be within ± 20% of the mean for each sex.

7.3 Route and Rationale of Test Article Administration:

The route of administration will be intravenous since this is an acceptable route of administration to assess systemic exposure.

7.4 Organization of Test Groups, Dosage Levels and Treatment Regimen:

7.4.1 Organization of Test Groups:

The dosage levels will be determined from the results of previous studies and will be provided by the Sponsor Representative after consultation with the The following diagram presents the study group arrangement.

Pharmacokinetic (Blood Collection) Groups:

Group Number	Treatment	Dosage Level (mg/kg)	Dosage Concentration (mg/mL)	Dosage Volume (mL/kg)	Number of Animals	
					Males	Females
1		10	2	5	9	9

Excretion (Urine Collection) Groups:

Group Number	Treatment	Dosage Level (mg/kg)	Dosage Concentration (mg/mL)	Dosage Volume (mL/kg)	Number of Animals	
					Males	Females
1		10	2	5	3	3

Data for pharmacokinetic groups and excretion groups will be collected in separate computer protocols.

7.4.2 Vehicle:

Sterile water for injection will be used as the vehicle.

7.4.3 Treatment Regimen:

Animals will be appropriately restrained and administered dosing solutions by a slow bolus intravenous injection (sterile needle and syringe) via a lateral tail vein. A constant volume of 5 mL/kg will be used. The treatment period will be 1 day. Day 0 will be the day of dosing.

7.5 Preparation and Analysis of Test Article Preparations:

7.5.1 Test Article Preparation:

The test article will be prepared for dosing as weight-to-volume mixtures in a vehicle and filter-sterilized in a laminar flow hood. No correction for purity will be made. A complete description of the method of test article preparation will be documented in the Study records and described in the final report. Test article formulations will be prepared within 1 week of use for dosing and stored refrigerated. The formulation will be removed from storage and allowed to remain at room temperature for at least 1 hour before dosing.

7.5.2 Homogeneity and Stability of Test Article Formulations:

Homogeneity assessments will not be performed, as the formulations are solutions. Analyses to demonstrate the stability of the test article formulation for the expected period of refrigerated storage between formulation and dosing will be conducted before the initiation of dosing.

7.5.3 Concentration Analysis:

Concentration will be confirmed during the dosing period. Samples will be drawn from the test article formulation. These will be submitted to

the nalyzed for test article concentration using a validated method.

The Analytical Chemistry report will be appended to the final report for this study.

8 EXPERIMENTAL OBSERVATIONS:

8.1 Viability Observations:

All animals will be observed for mortality/moribundity twice daily, once in the morning and once in the afternoon. Moribund animals will be euthanized to ensure that tissues will not be lost due to autolysis.

8.2 Detailed Physical Examination:

All animals will receive a detailed physical examination at least once during the pre-treatment period. Animals without signs will be noted individually.

8.3 Individual Body Weights:

Individual body weights will be recorded during acclimation, at pretest initiation, at randomization and on Day 0.

8.4 Individual Food Consumption:

Individual food consumption will be recorded during the pretreatment period only.

8.5 Toxicokinetics for Elimination:

Blood samples will be obtained from the blood collection groups for determination of concentration of the erum at the time points outlined in the following table:

Intervals	1 Day 0
Time points post-dosing	• Prior to a dosing and approximately 2, 10, 20 and 30 minutes and 1, 3, 5, 7, 24 and 48 hours after dosing • Clock times of collection recorded
Number of Animals	• 3 animals/sex bled per time point • Each animal sampled no more than three times in a 24 hour period (unless a terminal collection followed by euthanasia).
Sample Collection	Retro-orbital sinus under isoflurane (inhalation) anesthesia.
Target Blood Volumes	• 0.5 mL/time point • collect into non-chilled sampling tubes
Anticoagulant	None.
Sample Handling	Samples will be allowed to clot at room temperature, after which they will be kept chilled (ice water bath, as appropriate) after collection and during processing.
Serum Preparation	Beckman 6R centrifuge 2400-2700 rpm at -4°C
Aliquots	Recover all serum possible and place in Nunc© plastic vials.
Label information	Study number, dose group, animal number, sample type, date of collection, time of collection.
Storage	• Approximately -20°C until analysis • Time placed in freezer recorded

Moribund animals will be euthanized by CO_2 inhalation. Animals found dead or euthanized *in extremis* after start of dosing will be examined to determine possible cause of death and discarded. Following the final blood collection, all animals will be euthanized by carbon dioxide inhalation and discarded.

Urine collection animals will be transferred into plastic metabolism cages for urine collection following dosing. Urine will be collected on wet ice over the following intervals: 0-6, 6-12 and 12-24 hours post-dosing. The volume of each urine sample will be recorded, after which the urine samples will be frozen with minimal delay in a freezer set to maintain temperature of approximately -20°C until preparation for analysis. Following the final urine collection, all animals used for urine collection will be euthanized by carbon dioxide inhalation and discarded.

During method validation, stability of assessed in processed samples, during long-term frozen storage (-20°C), after short-term (at least 4-

hour) room temperature storage and during the freeze-thaw process. At least triplicate samples will be analyzed and the mean response will be compared against that of the freshly-prepared samples (the sample response may be analyzed as concentration, peak area, or peak area ratio, etc, depending on the stability analysis). If a significant degradation (>15% reduction in the mean response) occurs under any of the tested conditions, then special precautions will be taken.

Serum and urine samples will be analyzed for EEA concentration, by the Analytical Chemistry Department at a validated LC/MS/MS method.

Subsequently, pertinent toxicokinetic parameters, such as C_{max}, AUC, and elimination half-life, will be determined as data permit, for each of the test articles following a single dose of the test material.

9 STATISTICAL METHODS:

No statistical test will be performed.

10 QUALITY ASSURANCE:

The study will be audited by the ... progress to assure compliance with the study protocol and protocol amendments, WIL Standard Operating Procedures and the appropriate provisions of the U.S. EPA TSCA and FIFRA Good Laboratory Practice Standards published in the Federal Register (40 CFR Part 792 and 40 CFR Part 160) and the OECD Good Laboratory Practice Regulations [C(97)186 Final]. The raw data and draft report will be audited by the WIL Quality Assurance Unit prior to submission to the Sponsor Representative to assure that the final report accurately describes the conduct and the findings of the study.

This study will be included on the list of regulated studies.

11 RECORDS TO BE MAINTAINED:

All original raw data records, as defined by be stored as described in Section 12

12 WORK PRODUCT:

The Sponsor will have title to all documentation records, raw data, slides, specimens and other work product generated during the performance of the study. Any remaining formulation and/or toxicokinetic samples will not be archived, but will be discarded after issuance of the final report. All work product, including raw paper

data, pertinent electronic storage media and specimens, will be retained for a period of 10 years following issuance of the final report in th

monthly archiving fee for retention of all work product. All work product will be stored in compliance with regulatory requirements.

Any work product, including documents, specimens, and samples, that are required by this protocol, its amendments, or other written instructions of the Sponsor, to be

packaged and labeled as defined by delivered to a common carrier not be responsible for shipment following delivery to the common carrier.

13 REPORTS:

The final report will contain a summary, test article data, methods and procedures, appropriate individual animal and summary data tables, a copy of the protocol and amendments (if any) and an interpretation and discussion of the study results. The report will contain all information necessary to conform with current EPA specifications.

ide one (1) copy of an Audited Draft Report, submitted in a timely manner upon completion of the study prior to issuance of the final report. One (1) revision will be permitted as part of the cost of the study, from which Sponsor's reasonable revisions and suggestions will be incorporated into the Final Report, as appropriate. Additional changes or revisions may be made, at extra cost. It is expected that the Sponsor will review the draft report and provide comments a two (2) month time frame following submission. will submit the Final Report within one (1) month following receipt of comments. If the Sponsor's comments and/or authorization to finalize the report have not been received a n one year following submission of the draft report, elect to finalize the report following appropriate written notification to the Sponsor. Two (2) electronic copies of the Final Report on CD-R will be provided; requests for additional electronic or paper copies of the Final Report may result in additional charges.

14 ANIMAL WELFARE ACT COMPLIANCE:

This study will comply with all applicable sections of the Final Rules of the Animal Welfare Act (AWA) regulations (9 CFR Parts 1, 2 and 3). The Sponsor should make particular note of the following:

- The Sponsor Representative's signature on this protocol documents for the Study Director the Sponsor's assurance that the study described in this protocol does not unnecessarily duplicate previous experiments.

- Whenever possible, procedures used in this study have been designed to avoid or minimize discomfort, distress or pain to animals. All methods are described in this study protocol or in written laboratory standard operating procedures.

- Animals that experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized as deemed appropriate by the veterinary staff and Study Director. The Sponsor will be advised by the Study Director of all circumstances which could lead to this action in as timely a manner as possible.

- Methods of euthanasia used during this study are in conformance with the above-referenced regulation.

- The Sponsor/Study Director has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals and has provided a written narrative description (AWA covered species) of the methods and sources used to determine that alternatives are not available.

15 PROTOCOL MODIFICATION:

Modification of the protocol may be accomplished during the course of this investigation. However, no changes will be made in the study design without the verbal or written permission of the Sponsor. In the event that the Sponsor verbally requests or approves a change in the protocol, such changes will be made by